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ABSTRACT

Presented are six papers pertaining to the management of science, research, and development by federal agencies. The papers were prepared by students in a management of science course offered at the American University, Washington, D.C. Federal agencies reviewed include: National Aeronautics and Space Administration (NASA); Department of Agriculture; Environmental Protection Agency; Food and Drug Administration; Energy Research and Development Administration; and National Institutes of Health. (SL)

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In a graduate course on the Public Management of Science each student undertook to prepare a descriptive monograph on the management of science in a Federal agency. The objective was to provide a self-learning experience and a useful exchange of findings within the class--to make up for the lack of literature on the subject. A second objective was to provide a better base of documentation for students in subsequent offerings of the course.

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PUBLIC MANAGEMENT OF SCIENCE:

CASE STUDIES

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COLLEGE OF PUBLIC AFFAIRS
THE AMERICAN UNIVERSITY
WASHINGTON, DISTRICT OF COLUMBIA 20016

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INTRODUCTION

Directions, emphasis and vigor of science in the United States are determined very largely by Federal agency research, sponsorship of research and related development, regulatory and action programs.

Yet there is very little descriptive and analytical literature about the Federal management of science. Insights are provided by Congressional documents, agency reports, and scattered scholarly works of history, case study or criticism.

In a graduate course on the Public Management of Science each student undertook to prepare a descriptive monograph on the management of science in a Federal agency. The objective was to provide a self-learning experience and a useful exchange of findings within the class--to make up for the lack of literature on the subject. A second objective was to provide a better base of documentation for students in subsequent offerings of the course.

As the project became known outside the immediate class, there were inquiries for copies of the agency reports.

In response to these inquiries the students have agreed to publication and dissemination through the National Technical Information Service of the U. S. Department of Commerce.

It is important that all readers understand that these papers are the result of only one of several assignments in a one-semester university course. They have not been professionally edited. Nor have they necessarily been reviewed by the agency. They should be considered as first findings, hopefully useful to those who are interested in the subject.

The published papers treat the National Aeronautics and Space Administration, the Department of Agriculture, the Environmental Protection Agency, the Food and Drug Administration, the Energy Research and Development Administration and the National Institutes of Health. In addition in the reference collection on Science/Technology Policy and Administration of American University's College of Public Affairs are reports on the Department of Defense, the Department of the Army, the Department of the Navy, the Department of the Air Force, and the Department of the Interior.

Credit for these reports, published and unpublished, goes to the students. Paul Rothberg was teaching assistant for the course and his counsel was helpful. Jeanne M. Murray prepared the collection for deposit with NTIS.

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October 1, 1976

1

THE MANAGEMENT OF SCIENCE AT THE NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

by

Stanley N. Siegel

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INTRODUCTION

The National Aeronautics and Space Administration was established on October 1, 1958. The overlying reason for its establishment was the successful orbiting of Sputnik I by the USSR on October 4, 1957.[1] NASA was not a completely new agency. It was brought forth out of the National Advisory Committee for Aeronautics (NACA), which was established in 1915.

The orbiting of Sputnik revealed Russia's competence in rocket technology to be much greater than was believed at the time. More importantly, it confirmed Russia's claim of August, 1957, that it had an ICBM capability. Not only did the Sputnik orbiting tarnish the image of the U. S. as the world's technology leader, but it magnified the Russian threat to the national security of the United States.

One should not be misled by the above remarks. The U. S. had significant rocket activity of its own at that period. These activities were being carried out by the military services. Five missile systems accounted for the bulk of this activity. The Air Force was developing the Atlas and Titan ICBMs and the Thor IRBM; the Army, the Jupiter

IRBM; and the Navy, the Polaris, IRBM. At the time the first Sputnik was orbited, the U. S. had had two unsuccessful test flights of the Atlas, four unsuccessful test flights out of five of the Thor, and two unsuccessful test flights out of four of the Jupiter.[2]

The only significant satellite program being carried out by the U.S. at that time was under the auspices of the U.S. IGY Committee of the National Academy of Sciences and the DOD Committee on Special Capabilities. It was managed by the Office of Naval Research and called Project Vanguard. This project suffered from decisions which gave it a "shoestring" status in terms of national priorities and resources.[3] In comparison with Sputnik, Project Vanguard came to be viewed as something too little, too late.

On March 5, 1958, President Eisenhower approved the recommendations of his advisory Committee on Government Organization that the "leadership of the civil space effort be lodged in a strengthened and redesignated National Advisory Committee for Aeronautics," and that legislation be enacted "to give NACA the authority and flexibility" to carry out its expanded responsibilities.[4] Beginning with the March 5th memo and culminating in the passage by Congress of the National Aeronautics and Space Act of 1958, NASA was created. It was to be the focal point of U. S. aeronautics and space research and technology activities, initially inheriting all of the NACA facilities and programs and designated facilities and programs of DOD.[5]

Some of the significant sections of the National Aeronautics and Space Act of 1958, relating to NASA's management of science are as follows: the functions of NASA as enumerated in Title II, Section 203, were only three in number; (1) to "plan, direct and conduct aeronautical and space activities," (2) to arrange for the participation of the scientific community in these activities, and (3) to widely disseminate information about these activities. The powers of NASA, as authorized in Section 203, were to make rules, hire employees, acquire property, accept gifts, enter into contracts, enter into agreements with other agencies, utilize the services of advisory committees, hire consultants, coordinate with other public and private organizations, etc. Two other sections under Title II warrant mentioning. Section 205 gave legislative recognition to the need for NASA to cooperate with other nations, providing it is done within the framework of U. S. foreign policy, and Section 206 provided for an annual Presidential report to Congress on the nation's space program and a semiannual NASA report to the President and Congress on NASA space activities. Title III, Section 305, the most lengthy section in the Act, dealt with patents. Included was a provision for the establishment, within NASA, of an Inventions and Contributions Board which was to consider waivers to the general agency policy that inventions made using NASA resources (in-house or contract) became U. S. property, as do the patents based on the inventions. Section 306 gave the NASA Administrator the power to make monetary awards for valuable scientific and technical contributions to NASA. Awards were to be based on the recommendations of the Inventions and Contributions Board.

During its glory years, in the midst of the Apollo Project, NASA had grown to enormous proportions. In FY-66, the NASA budget was $11.4 billion in FY-77 dollars (figure 3), or 4.4% of the total Federal budget (figure 4). The agency employed 79,265 people which included civil service and support contractor, "in-house" personnel. Compare these figures with FY-77. The proposed budget is $3.7 billion or 0.93% of the Federal budget and NASA employes 45,751 people.[6]

Each year approximately 85 percent of NASA's budget appropriation is expended in the form of procurement awards to business firms, educational and nonprofit institutions and with other Government Agencies. In Fiscal Year 1974, NASA's procurement awards totalled $2.71 billion, of which $2.42 billion went to business firms either directly from NASA, through other Government Agencies in NASA's behalf, or in subcontract awards from NASA's contractor-operated Jet Propulsion Laboratory. Research and Development (R&D) is the most important phase of NASA operations, accounting for more than two out of every three dollars in current budget allocations.[7]

To date the manned space program has been NASA's greatest development effort. It is my opinion that they believe the manned program has not returned, in research and technology results, applications, etc., benefits nearly what has been spent on it. The unmanned programs on the other hand, have returned far more in benefits than have been spent. These, I must reiterate, are only impressions which I received during preparation of this paper.

Another impression I have had concerning NASA for many years is that NASA has always appeared to be a publicity-seeking agency. Every opportunity for publicity of any kind in the lay media is exploited. Naturally, one would expect events such as the first man landing on the moon to be of great interest and provide a feeling of national pride to the people of the U. S. Therefore, one would expect the media to over report an event of that magnitude. However, NASA, in the past, has sought to publicize events of much lesser magnitude in the lay media. It is almost as if through publicity NASA has sought to justify its great expenditures of public funds to the citizens of the United States. I have been careful to differentiate the coverage of NASA in the lay media vs. its coverage in the scientific media. Here NASA does a Yeoman's job with its Technology Utilization Program, which will be discussed in Chapter 10, Technology Transfer.

Prior to leaving this subject, in an effort to show my point, allow me to ask the reader: what have you learned about NASA, which had an

FY-76 budget of $3.5 billion [8] in the lay media, as compared to what you have learned about the National Science Foundation, with an FY-76 budget of $0.72 billion, [9] or the National Institutes of Health, with an FY-76 budget of $2 billion? [10]

With the above remarks out of the way, let us get to the management of science at NASA. Research for this paper has been based primarily on public documents, internal NASA documents and interviews with NASA personnel. Inasmuch as certain documents are more accessible than others and that some individuals made themselves more available for interviews, may explain the unevenness of this paper.

The paper is intended to be an overview of the procedures and policies used in the management of science at NASA. I do not pretend to have considered every aspect of the science management process. NASA, being a decentralized agency, has many policies peculiar to specifics of its Centers. In general, these peculiar policies have not been addressed, as they are considered to be beyond the scope of the paper. Comment has been made throughout the paper concerning various practices and policies where I have deemed them appropriate, and a general comment has been expressed in the Epilogue as to whether, in my opinion, NASA policies, procedures, organization and administration help the United States meet its research and development objectives in a manner to ensure this nation's continued leadership in space and aeronautical technology.

The first chapter covers NASA's present organization and the major functions of each of the NASA field installations. The next three chapters discuss the agency's fiscal policy including the budget process, the budget itself, and procurement and contracting. Chapters 5 and 6 discuss NASA's project review and approval system and the management of NASA programs. Innovation is most important in successful science management. The major portion of the paper discusses innovation, patents, unsolicited proposals, technology transfer and assessment. Chapter 12 considers NASA's political institution relationships including federal, regional, state, municipal and international. The final chapter covers manpower management at NASA.

Chapter 1

NASA ORGANIZATION

When NASA was established as an operating agency in October 1958, it consisted almost entirely of the National Advisory Committee on Aeronautics (NACA) organization which it absorbed. NASA pursued fundamental as well as applied engineering research, but it was not isolated from either contact with, or appreciation of, operational problems confronting user organizations such as the airlines, the aircraft industry, and the military air services.

The NACA organization consisted of three major aeronautical laboratories - Langley, Ames, and Lewis - and a small Washington-based headquarters which exercised a minimum of control or direction over the laboratories. In NACA, technical initiative and depth of technical competence were located in the laboratories. Under NASA, greater strength and authority were placed in Headquarters. During its early years, NASA Headquarters drew heavily upon the former NACA laboratories to staff its growing programs.

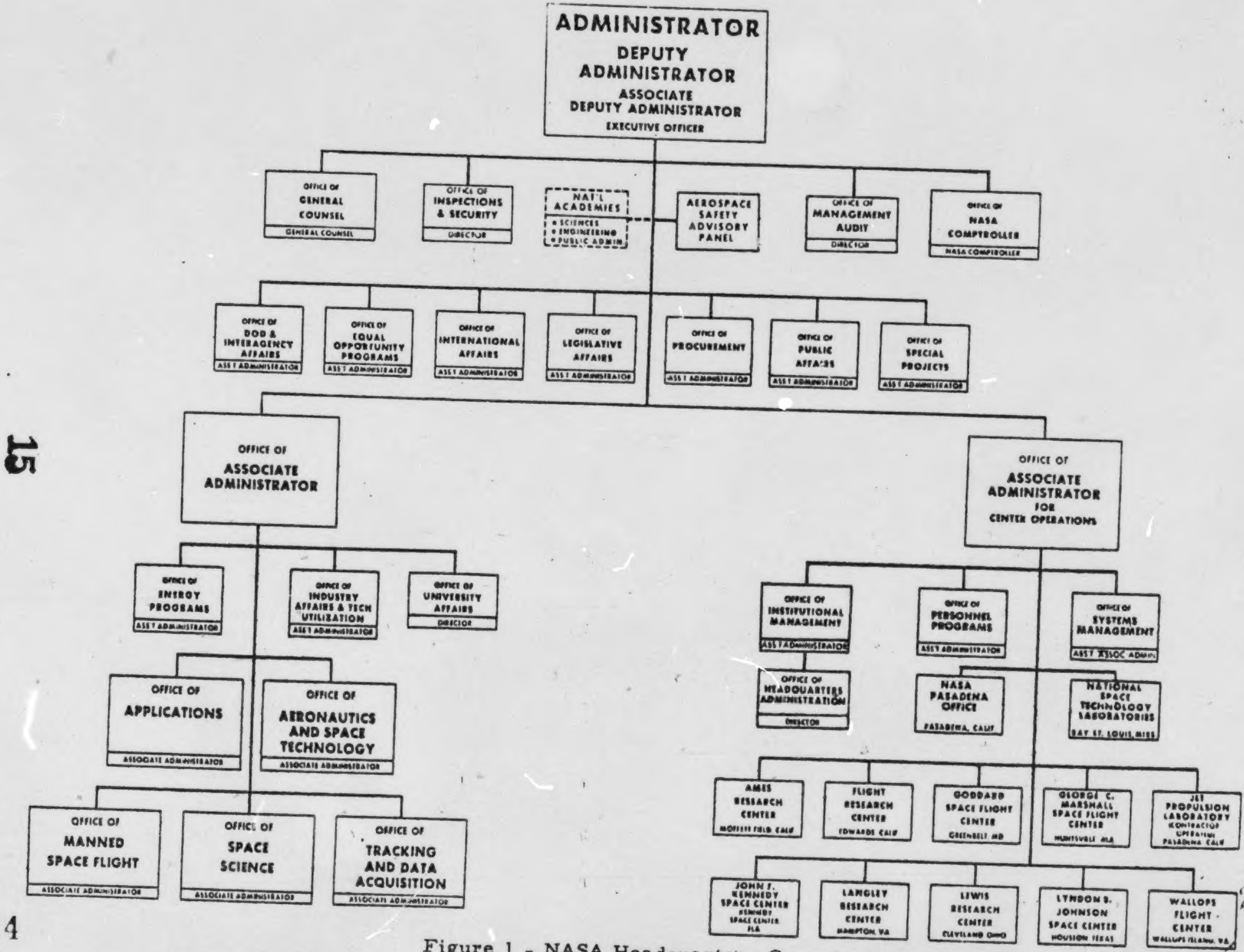
NASA's approach to project management was influenced in two important respects by NACA. First, there was the partnership style of operation whereby NASA and industry worked closely together on technical problems, in contrast to the more typical government-industry arms-length relation of customer and vendor. Second, most of the technical initiative and detailed technical decision making was left to the field installations.

From its beginning, NASA has been organized by: (1) top management (the Administrator and his immediate office); (2) functional support for top management and the agency in general; (3) program offices (developing and controlling the major program activities); and (4) the field installations (largely responsible for the day-to-day conduct or management of the programs and their components - whether in-house, at universities, or at contractors). The present organization is, in most respects, the same (figure 1). [11]

The Office of Organization and Management, and the Associate Deputy Administrator and their organizations directly support the Administrator and his Deputy in their executive responsibilities and NASA generally, in functions ranging from planning, through contracting and budgeting, to legislative or international affairs. These activities are considered "functional" support.

The Offices of Manned Space Flight, Space Science, Tracking and Data Acquisition, Applications, Aeronautics and Space Technology and Energy Programs report to the Associate Administrator and are responsible for the development, justification and management of

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION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NAT'L ACADEMIES
• SCIENCES
• ENGINEERING
• PUBLIC ADMIN
AEROSPACE SAFETY ADVISORY PANEL
OFFICE OF MANAGEMENT AUDIT
DIRECTOR
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ASSOCIATE ADMINISTRATOR
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OFFICE OF SPACE SCIENCE
ASSOCIATE ADMINISTRATOR
OFFICE OF TRACKING AND DATA ACQUISITION
ASSOCIATE ADMINISTRATOR
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LANGLEY RESEARCH CENTER
HAMPTON VA
LEWIS RESEARCH CENTER
CLEVELAND OHIO
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HOUSTON TEXAS
WALLOPS FLIGHT CENTER
WALLOPS ISLAND, VA

Figure 1 - NASA Headquarters Organization

NASA's programs in each of these areas. These activities are considered "program" or substantive activities. Also reporting to the Associate Administrator are the Office of Industry Affairs and Technology Utilization, and the Office of University Affairs.

The Office of Manned Space Flight is responsible for all NASA activities directly involving manned space flight missions. This projects a program building on the success of the Apollo and Skylab missions to demonstrate an international cooperative space docking mission and to develop a new space transportation system significantly improving the access of man and instruments to space.

The Office of Space Science is responsible for all NASA activities involving the conduct of scientific investigations in space. These activities include the planning, development and conduct of space missions in physics and astronomy, lunar and planetary exploration as well as the management of the launch vehicle program essential to the support of automated missions.

NASA has also established an Office of Energy Programs to provide direction to its research, technology and development programs which apply aerospace technology and management techniques to critical national energy needs, including support of other Federal agencies, particularly ERDA.

The Office of Tracking and Data Acquisition (OTDA) is responsible for the development and operation of communications, tracking, data acquisition, and data processing facilities, systems, and services required for support of NASA flight programs. OTDA is also assigned NASA-wide responsibility for administrative communications management and frequency management.

The Office of Applications is responsible for all research and development activities that demonstrate the application of space related technology, systems and other capabilities which can be effectively applied and used in the civil sector for practical benefits to mankind. The R&D activities are grouped in the following areas: Weather and Climate, Pollution Monitoring, Earth Resources Survey, Earth and Ocean Physics Applications, Space Processing, Communications, Data Management, and Applications Experiments and Studies.

The Office of Aeronautics and Space Technology is responsible for the planning, direction, execution, evaluation, documentation, and dissemination of the results of all NASA research and technology programs that are conducted primarily to demonstrate the feasibility of a concept, structure, component, or system and which may have general application to the nation's aeronautical and space objectives. This office is also responsible for coordinating the agency's total program of supporting research and technology related to carrying out specific flight missions in order to avoid unnecessary duplication and to insure an integrated and balanced agency research program.

Each field installation reports to the Associate Administrator for Center Operations for general institutional management. This office also provides the administration requirements for Headquarters.

The major functions of each of the field installations is described below.[12]

AMES RESEARCH CENTER

The programs of the Center are directed at research and development of technology in the fields of aeronautics, space science, life science, and spacecraft technology. Current emphasis at Ames in aeronautics is on short takeoff and landing (STOL) and vertical takeoff and landing (VTOL) technology. In space science, in addition to Ames' own programs which include studies of solar physics, planetary environments, and geophysics, Ames produces specially outfitted aircraft - in effect, airborne laboratories - to serve as flying instrument platforms for the use of scientists from all over the world in studies of both space and Earth. Ames has management responsibility for the Pioneer series of spacecraft, six of which have been launched into solar orbit, with two on their way to Jupiter. In its life science laboratories, scientists study the origin of life, the relationship between man and aircraft, and provide medical criteria for allowing man on space vehicles. In spacecraft technology, Ames supports NASA's Space Shuttle program by providing research on heat protection systems and by providing wind tunnel investigations of the stability and heating of the various configurations proposed for Space Shuttle. In cooperation with other Federal, State and local agencies, Ames conducts pilot programs and prototype investigations of applications of space technology to Earth-bound problems.

FLIGHT RESEARCH CENTER

The Flight Research Center mission includes research and test activities on problems of aircraft and flight research vehicle takeoff and landing, low speed flight, supersonic and hypersonic flight, and flight vehicle reentry to verify predicated vehicle and flight characteristics, and to identify unexpected problems in actual flight and to correlate theoretical or wind tunnel research studies. This includes proof of concept investigations and exploratory research into new aircraft designs such as the supercritical wing, hypersonic wing structure technology, and advanced aeronautical systems; aerothermalelastic research studies, propulsion research, and exploratory research projects involving supersonic and hypersonic flight; studies in the development of new flight test techniques and approaches involving remotely piloted research vehicles; flight investigations involving the use of wingless lifting body aerospace vehicles; research on current aircraft problems including life sciences studies into aircraft ride qualities, wing-wake-vortex operating studies, and aerodynamic and propulsion system noise studies; and studies into terminal area operations of the Space Shuttle vehicle and flight investigations involving the horizontal flight test of the Space Shuttle.

GODDARD SPACE FLIGHT CENTER

The Goddard Space Flight Center conducts and is responsible for automated spacecraft and sounding rocket experiments in support of basic and applied research. Active programs underway include the following scientific disciplines: aeronomy, energetic particles and fields, ionospheric physics, astronomy, planetary atmospheres, geophysics and solar physics. In the area of applied sciences, the Center has the mission of developing meteorological and advanced technology satellites.

Satellite programs managed by GSFC include the Earth Resources Technology Satellite, Nimbus, Applications Technology Satellite F, Atmosphere Explorer, Interplanetary Monitoring Platform, Small Astronomy Satellite and Synchronous Meteorological Satellite.

Goddard manages the Spaceflight Tracking and Data Network (STDN) and the NASA Communications Network (NASCOM), which track and acquire data and maintain communications with manned and automated spacecraft. In addition, Goddard manages the development and procurement of the Delta Launch Vehicle and operates the Goddard Institute for Space Studies.

JET PROPULSION LABORATORY

The Jet Propulsion Laboratory (JPL) is a Government owned facility that is staffed and managed by the California Institute of Technology. It is engaged in activities associated with deep space automated scientific missions, tracking data acquisition, data reduction and analysis required by deep space flight, advanced solid propellant and liquid propellant spacecraft engines, advanced spacecraft guidance and control systems, and integration of advanced propulsion systems into spacecraft. The Laboratory designs and tests flight systems, including complete spacecraft, and also provides technical direction to contractor organizations. JPL operates the worldwide deep space tracking and data acquisition network (DSN) and maintains a substantial program to support present and future NASA flight projects and to increase capabilities of the Laboratory.

JOHNSON SPACE CENTER

The Johnson Space Center (JSC) was established in September 1961, at Houston, Texas as NASA's primary Center for design, development, and manufacture of manned spacecraft; selection and training of astronaut crews; and the conduct of spaceflight missions. JSC modified the Apollo spacecraft to support the Apollo/Soyuz Test. JSC has been designated as the lead NASA Center for Space Shuttle and for the Earth Observations Program. In all this effort, JSC is assisted and supported by other NASA Centers, various other civilian Government agencies, the Department of Defense, many universities and many other nations in the free world. The Center is also responsible for direction of the operations at the White Sands Test Facility in New Mexico.

KENNEDY SPACE CENTER

The Kennedy Space Center serves as the primary Center within NASA for the test, checkout and launch of space vehicles. This presently includes launch of manned and unmanned vehicles at the Kennedy Space Center, the Air Force Eastern Test Range and the Air Force Western Test Range. The Center is now concentrating on development of Space Shuttle launch facilities and launchsite ground support equipment as well as research and operational unmanned launches.

KSC WESTERN TEST RANGE OPERATIONS DIVISION

The John F. Kennedy Space Center, Western Test Range Operations Division, provides launch operations management for all NASA, university and Government agency unmanned programs at the Air Force Western Test Range. This includes all operational aspects of integration, test, checkout, and launch of Scout and Delta Vehicles. The Division also provides technical, logistic and administrative support to other NASA elements located at the Western Test Range.

LANGLEY RESEARCH CENTER

A substantial percentage of the Center's research work is development of advanced concepts and technology for future aircraft, with particular emphasis on environmental effects, performance, range, safety and economy. Examples of this research are projects involving the supercritical wing composite structural materials and automatic flight control systems. Langley is involved in the development of technology for helicopters and avionic systems for reliable operations in terminal areas of the future. An ongoing program is the improvement of supersonic flight capabilities for both transport and military aircraft. The Center works with the general aviation industry to help solve problems concerning aircraft design and load requirements and to improve flight operations.

Langley has complete responsibility for NASA's Viking, a spacecraft that will orbit and land on Mars in 1976. Viking will permit a detailed study of Martian geophysics, atmospheric characteristics, surface properties; and, most significantly, experiments that will indicate if life forms are present on the planet. Unmanned spacecraft programs are supported by the development of experiments and sensors, communications, and data handling systems. A ground-based research program involves the investigation of effects such as heat, vacuum, noise and meteroids on space vehicles; the use of advanced composite and polymeric materials for structures and thermal control systems; and improved technology for antenna and power amplifiers, batteries, high-capacity computer memories, logic circuits and other advanced microelectronic devices.

LEWIS RESEARCH CENTER

The Lewis Research Center conducts research and development on advanced propulsion and power generation systems. This includes work on turbojet engines, supersonic aircraft, high energy chemicals and electric rocket engines. The Center conducts research on power systems for converting chemical and solar energy into electricity. The major research tools at the Lewis Research Center are designed to simulate flight conditions and range from atmospheric wind tunnels to large space environmental facilities (vacuum tanks). A major effort in space power is concentrated on turboelectric, thermoelectrical and thermionic energy conversion systems.

LeRC PLUM BROOK OPERATIONS DIVISION

The Plum Brook Operations Division operates as an adjunct of the Lewis Research Center for large-scale testing of nuclear propulsion components in NASA's nuclear test reactor and for full-scale static and dynamic tests of completed space vehicles and propulsion components.

Termination of nuclear propulsion and power programs resulted in the closing of the Reactor Facility at the end of fiscal year 1973. The greatest portion of NASA activities at Plum Brook were terminated at the end of the fiscal year 1974. All major facilities, with the exception of the Space Power Facility, will be maintained in a standby condition. Further utilization of the facility is presently being considered by the Air Force and Navy for testing of space satellites. All other facilities not required to support this effort, including utilities and systems, will be maintained in a standby condition.

MARSHALL SPACE FLIGHT CENTER

The primary mission of MSFC is to develop and provide space transportation systems, orbital systems, scientific payloads, and other systems for present and future space exploration. The Center is also responsible for the direction of operations at the Michoud Assembly Facility and the Slidell Computer Complex.

MICHOUD ASSEMBLY FACILITY

The primary mission of the Michoud Assembly Facility is the systems engineering, engineering design, manufacture, fabrication, assembly, and related work for Saturn boosters and Space Shuttle elements.

NATIONAL SPACE TECHNOLOGY LABORATORIES

The present mission at the NSTL is to support Space Shuttle main engine testing and Space Shuttle orbiter propulsion system testing, as well as to provide NASA and other Government agencies located there such capabilities as are necessary to conduct remote sensing, environmental, and related research and technical activities.

SLIDELL COMPUTER COMPLEX

The Slidell Computer Complex is primarily responsible for fulfilling the computational requirements of NASA and the contractor-operated plants at the Michoud Assembly Facility and the National Space Technology Laboratories. These requirements are in the areas of scientific, management, and engineering automated data processing and in static and flight test data reduction evaluation.

WALLOPS FLIGHT CENTER

Wallops Flight Center (WFC) is responsible for planning and conducting applied research and development with emphasis on scientific payload development, instrumentation, facilities, and techniques utilized in rocketborne experiments, aeronautical and terminal area research projects, and ecological studies.

WFC prepares, assembles, launches, tracks, and acquires scientific information from space centers of NASA, other governmental agencies, colleges and universities, and the worldwide scientific community. Wallops personnel assist these scientific research teams with their projects and develop, as necessary, special types of instrumentation and equipment to complete the mission and manage NASA research projects. The Center utilizes launch vehicles ranging in size from the small Arcas and

Hasp meteorological rockets to the 72-foot Scout rocket with orbital capability in obtaining scientific data about the atmosphere and the near-space environment. Sixteen satellites have been launched from Wallops. WFC has launched approximately 8000 research vehicles consisting of from one to seven stages.

The Center exercises project management responsibility for several NASA-sponsored projects such as GEOS C, the Experimental Inter-American Meteorological Rocket Network (EXAMETNET), the Polar Cusp, the operation of remote site launching and tracking facilities, and the operation of NASA's portable range facilities for sounding rockets.

A portion of the Center's effort is devoted to NASA's program of international cooperation in space research. Foreign countries are provided with training programs for their personnel, assistance in activiation of launch~~sites,~~ and technical assistance and advice in launching experiments and in operation of their ranges.

WHITE SANDS TEST FACILITY

White Sands Test Facility (WSTF) was established for hazardous testing associated with Apollo propulsion and power systems. WSTF supports the Space Shuttle propulsion system, power system, and material testing and serves as the alternate site for storage of returned lunar rocks. WSTF supports other NASA Centers, other Government agencies and industrial firms. WSTF serves as range sponsor for NASA programs at the White Sands Missile Range.

Chapter 2

NASA BUDGET PROCESS

The process of developing the fiscal year budget at NASA is very similar to that of any executive branch agency. The length of time taken by NASA as well as certain specific steps may differ somewhat however. The NASA process will be discussed in terms of figure 2.

The total NASA budget process requires thirty-one months to accomplish. It is divided into three major steps: the Formulation Stage, which requires six months; the Review and Enactment Step, requiring thirteen months; and the Execution of Budget Programs, a twelve month process.

The Formulation Stage may be subdivided into six steps. Budget policies and assumptions are developed by the Administrator and his staff and released to the various estimating offices. In the case of R&D, these would be the offices under the Office of the Associate Administrator, figure 1. These offices, in conjuction with the various Centers, prepare a preview budget which is submitted to the Administrator. Following evaluation, a preliminary budget is submitted to the Office of Management and Budget (OMB). In conjunction with OMB, guidance consistant with administration policies is given the agency.

1. Formulation Stage (6 months)

   a. Develop and release budget policies and assumptions to estimating offices.
   b. Preview Budget - estimating offices submission to administrator.
   c. Preliminary budget submission to OMB.
   d. Develop budget administration manual guidlines consistent with policies, etc.
   e. Place the call for budget estimates
   f. Receive and review budget submissions

2. Review and Enactment Stage (13 months)

   a. President's budget - initial submission to OMB.
   b. OMB hearings
   c. Receipt of final markups from OMB.
   d. Prepare and submit final schedules for budget.
   e. Printing of federal budget document.
   f. Prepare justification books for Congress.
   g. Congressional committee hearings.
   h. Review and approval of program operating plans
   i. Enactment of appropriations.
   j. Receipt of appropriation warrants from treasury.
   k. Request for apportionment of funds from OMB.
   l. Preparation and issuance of resources authority warrants and allotments.

3. Execution of Budget Programs (12 months)

   a. Resources and program management funds (1 year)
   b. R&D funds (no year)

Figure 2 - NASA Budget Process (31 months)

This guidance is passed on to the various estimating offices within NASA. Final budget estimates are submitted to the Administrator and following review, the budget estimate is submitted to OMB. It must be noted that steps 1d, 1e and 1f are a continuous feedback process between NASA and OMB.

The Review and Enactment Stage may be divided into twelve steps. The NASA budget estimate is incorporated into the total President's Budget estimate. OMB conducts hearings on these estimates and prepares a marked-up version which is returned to NASA. This constitutes the budget which will be submitted by the President to the Congress. NASA then prepares schedules consistent with the marked-up budget and submits these to OMB. Following this step, the federal budget document is printed. Meanwhile, NASA is busy preparing justification and back-up material to be used at the Congressional Hearings. Authorization hearings for each agency are held by specific committees of both the House of Representatives and the Senate. The House Committee on Science and Technology and the Senate Committee on Aeronautical and Space Sciences, are responsible for NASA's funding authorization. Following authorization, appropriation hearings are held by both congressional houses. NASA's program operating plans are reviewed and approved. Subsequent to the congressional approval process, the total federal budget is reviewed and funding levels are set by Congress. Appropriation warrants are then sent by the Treasury to NASA. Following this, NASA requests apportionment of funds from OMB. Upon receipt of the funding apportionment, NASA Headquarters prepares and issues resource authority warrants and allotments to each of the NASA Centers.

Execution of Budget Programs is a twelve month process covering the fiscal year. Budget funds are divided into two types. The first type is resource and program management funds. These must be spent within the fiscal year of the budget. They are mainly used for functions internal to NASA. These functions include such areas as salaries, ADP, travel, etc. The second type of funds is referred to as "no year funds." These funds are used mainly for external contracting of R&D projects.

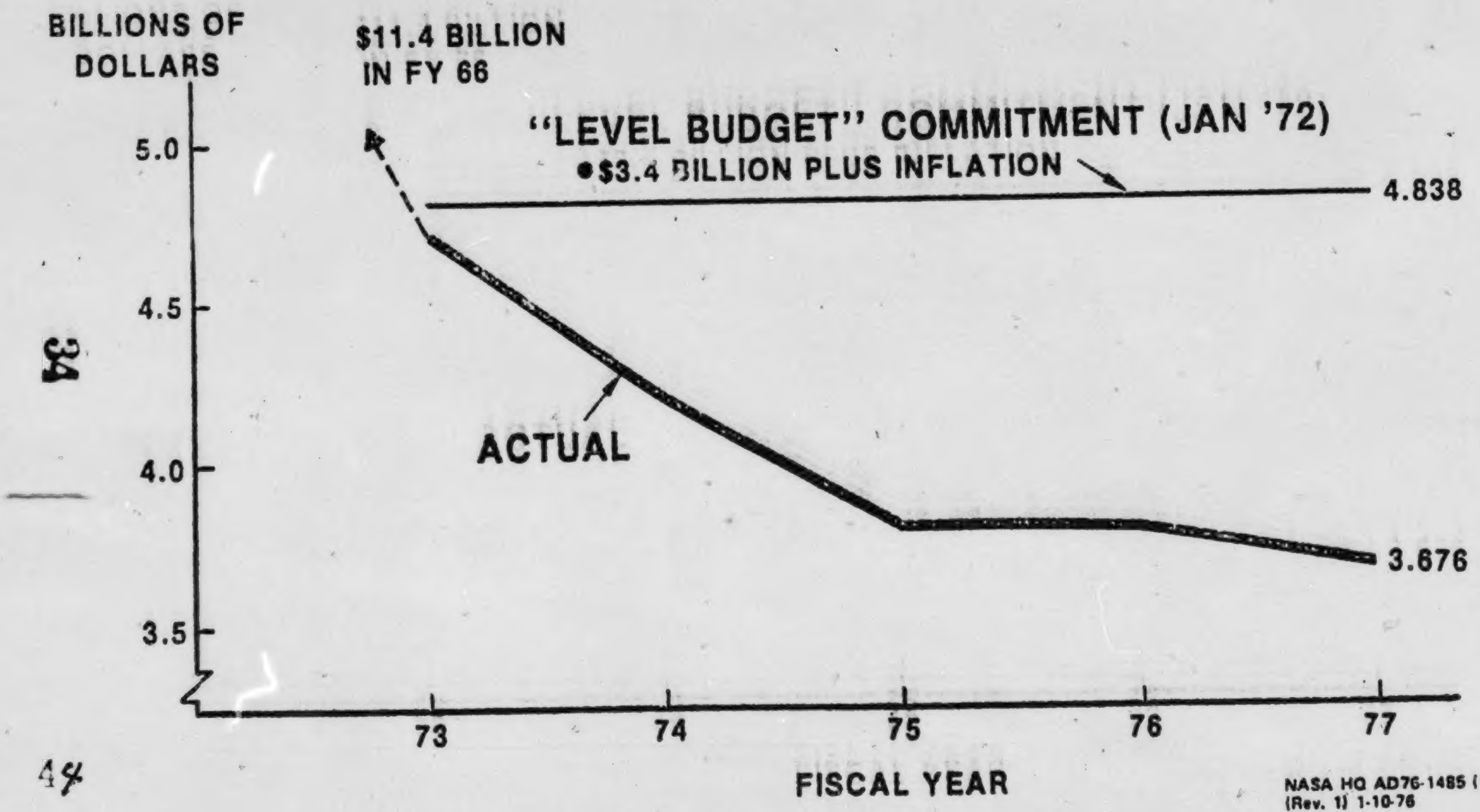
Chapter 3

NASA BUDGET [13]

Since the height of the Manned Space Program in the mid 1960's and our national goal promulgated by President Kennedy in 1960 to put a man on the moon by 1970, the NASA budget has been in steady decline. This decline is extremely evident in figure 3. In terms of constant FY-77 dollars, the NASA budget has fallen from $11.4 billion in FY-66 to a proposed $3.676 billion in FY-77. This is $1.162 billion less than the NASA "Level Budget" commitment of January, 1972. Over the past three years, this steady decline has leveled at approximately $3.7 billion in terms of constant FY-77 dollars. As shown in figure 4, the NASA budget amounts to 0.93% of the total federal budget. This compares with 4.4% in FY-66. The bulk of NASA's expenditures are for research and development, $2.76 billion in FY-77 or 75% of the total (table 1). A breakdown of the R&D budget by major programs is shown in table 2. The bulk of R&D budget expenditures are planned for the Space Shuttle Program ($1.65 billion). This amounts to almost 60% of the R&D budget. Aeronautics remains the second class citizen of the National Aeronautics and Space Administration. The FY-77 budget request contains

NASA BUDGET TRENDS

(OUTLAYS, CONSTANT FY 1977 DOLLARS)



NASA HQ AD76-1485 (1)
(Rev. 1) 1-10-76

Figure 3

NASA AS PERCENTAGE OF FEDERAL BUDGET OUTLAYS

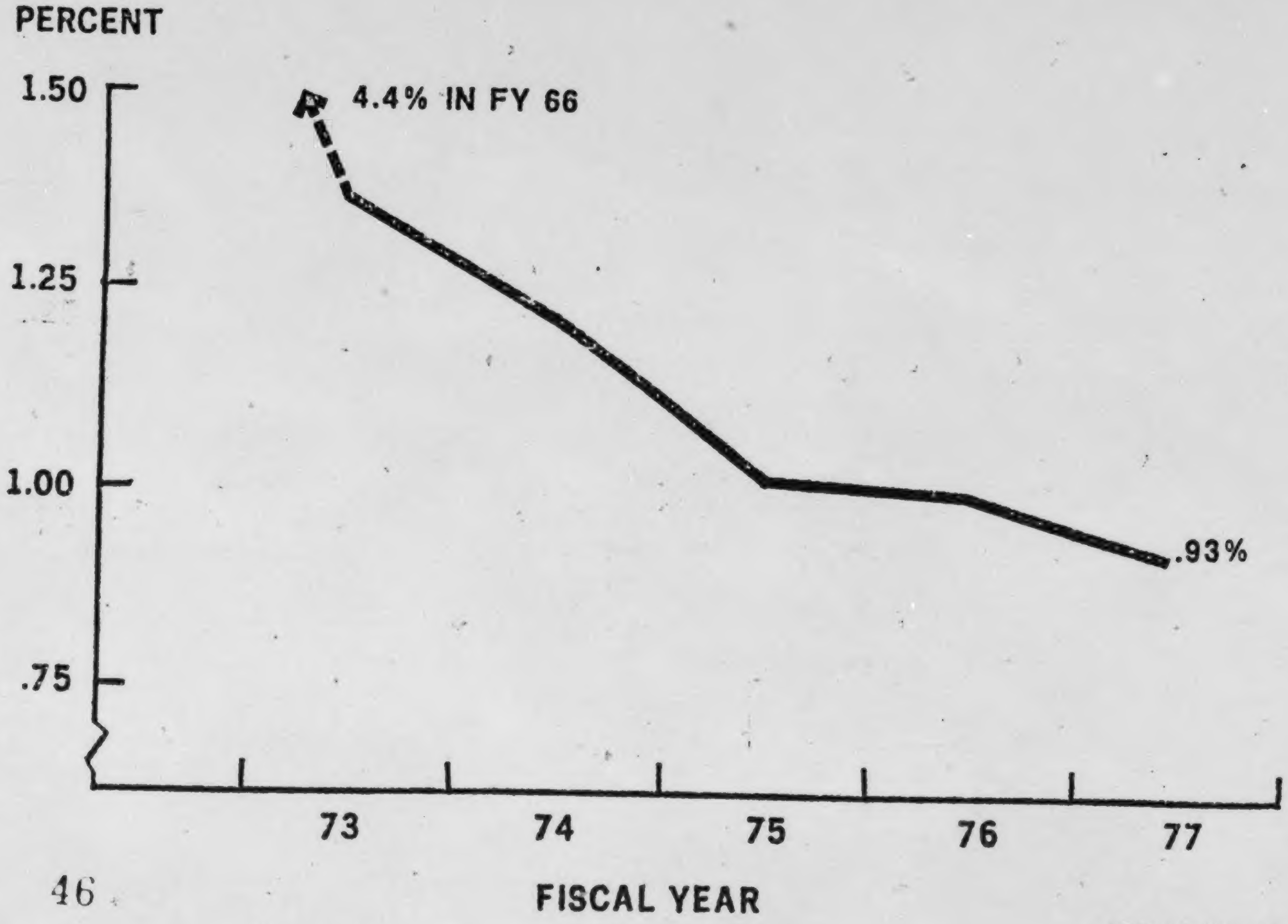


Figure 4

NASA HQ AD76-1464 (1)
(Rev. 1) 1-10-76

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

BUDGET SUMMARY
(Thousands of Dollars)

BUDGET PLAN	FY 1975	FY 1976	Transition Quarter	FY 1977
Research and development........	2,323,563	2,677,380	700,600	2,758,925
Construction of facilities......	142,655	82,130	10,750	124,020
Research and program management	764,704	795,498	220,795	814,055
TOTAL BUDGET PLAN.............	3,230,922	3,555,008	932,145	3,697,000
OUTLAYS..........................	3,266,708	3,517,200	908,700	3,676,000

Table 1

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

RESEARCH AND DEVELOPMENT PROGRAMS

BUDGET PLAN
(Thousands of Dollars)

	FY 1975	FY 1976	Transition Quarter	FY 1977
SPACE FLIGHT	1,235,800	1,560,500	406,500	1,644,700
Space shuttle..................	797,500	1,206,000	321,000	1,288,100
Space flight operations........	298,800	188,600	48,400	205,200
Expendable launch vehicles.....	139,500	165,900	37,100	151,400
SPACE SCIENCE	417,315	434,200	116,400	379,025
Physics and astronomy..........	136,315	159,300	43,500	165,800
Lunar and planetary exploration	261,200	254,100	67,700	191,100
Life sciences..................	19,800	20,800	5,200	22,125
APPLICATIONS	174,748	178,230	47,700	198,200
Space applications.............	174,748	178,230	47,700	198,200
AERONAUTICS AND SPACE TECHNOLOGY	237,765	250,250	63,100	271,100
Aeronautical research and technology.................	166,400	175,350	43,800	189,100
Space research and technology...	71,365	74,900	19,300	82,000
ENERGY PROGRAMS..................	4,435	5,900	1,500	---
Energy technology applications..	4,435	5,900	1,500	---
TRACKING AND DATA ACQUISITION.....	248,000	240,800	63,400	258,000
TECHNOLOGY UTILIZATION...........	5,500	7,500	2,000	7,900
TOTAL.......................	2,323,563	2,677,380	700,600	2,758,925

Table 2

$189 million in this category, or 6. 85% of the R&D portion. Table 3 breaks down the FY-77 budget request in terms of expeditures at each of the NASA Centers as well as NASA Headquarters. The major expenditures will occur at the Johnson Space Center where the major portion of the Space Shuttle Program is managed. The NASA budget should remain at a fairly constant level through FY-80, when the present Space Shuttle Program begins to wind down. Unless that program evolves into another major U. S. space effort, the NASA budget could decline sharply as the decade of the 80's begins.

Table 4 breaks the R&D budget (Table 2) down into greater detail. A cursory analysis of Table 4 reveals that a total of $560, 657, 000 of the NASA R&D budget is allocated for research activity, Table 5. This amounts to 20% of the total FY-77 NASA R&D budget. Table 6 shows the NASA FY-77 Construction of Facilities Program. From Table 6, a total of $10, 360, 000 or 8% of NASA construction can be identified for research purposes. NASA is an agency which performs both R&D and a 20-80 split in the two activities and appears to me to be more than reasonable. Add to this the fact that 8% of the NASA construction budget for FY-77 can be directly attributed to research, one must conclude that the researchers at NASA are well provided for.

ESTIMATED DISTRIBUTION OF TOTAL BUDGET PLAN
(Millions of Dollars)

	FY 1976	FY 1977
Johnson Space Center	1,133.1	1,110.6
John F. Kennedy Space Center, NASA	244.4	314.8
Marshall Space Flight Center	549.8	602.8
National Space Technology Laboratories	12.4	14.5
Goddard Space Flight Center	471.1	514.6
Wallops Flight Center	29.0	30.1
Jet Propulsion Laboratory	191.1	180.2
Ames Research Center	195.7	172.3
Hugh L. Dryden Flight Research Center	40.8	36.6
Langley Research Center	249.8	274.4
Lewis Research Center	247.8	244.2
NASA Headquarters	171.4	182.3
Undesignated	18.6	19.6
Total	3,555.0	3,697.0

Table 3

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

SPACE FLIGHT

BUDGET PLAN
(Thousands of Dollars)

	FY 1975 Actual	FY 1976	Transition Quarter	FY 1977
SPACE SHUTTLE	797,500	1,206,000	321,000	1,288,100
Orbiter	634,757	871,200	226,000	842,500
Main engine	95,300	135,500	36,000	193,800
Solid rocket boosters	21,143	69,300	18,000	82,600
External tanks	34,000	77,200	17,100	64,000
Launch and landing	12,300	52,800	23,900	105,200
SPACE FLIGHT OPERATIONS	298,800	188,600	48,400	205,200
Development, test and mission operations	170,200	161,100	41,100	169,900
Space transportation system operations capability development	3,000	9,500	2,000	17,300
Apollo Soyuz test project	109,600	---	---	---
Advanced programs	16,000	18,000	5,300	18,000
EXPENDABLE LAUNCH VEHICLES	139,500	165,900	37,100	151,400
Scout	12,300	10,600	3,400	10,700
Centaur	75,400	110,100	24,400	90,700
Delta	51,800	41,800	9,300	43,800
Atlas F	---	3,400	---	6,200
TOTAL SPACE FLIGHT	1,235,800	1,560,500	406,500	1,644,700

Table 4

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

SPACE SCIENCE

BUDGET PLAN
(Thousands of Dollars)

	FY 1975	FY 1976	Transition Quarter	FY 1977
PHYSICS AND ASTRONOMY...............	136,315	159,300	43,500	165,800
High energy astronomy observatories	42,900	59,218	13,500	36,600
Solar maximum mission..............	---	---	---	21,300
Solar maximum mission - advanced technological development........	1,515	1,000	700	---
Orbiting explorers.................	33,945	29,682	7,400	33,000
Solar observatories................	4,305	3,600	900	1,000
Astronomical observatories.........	2,216	2,500	600	2,600
Sounding rockets...................	19,976	20,000	6,200	20,700
Spacelab science program...........	3,330	4,600	3,500	10,000
Upper atmospheric research.........	---	3,500	1,000	11,600
Airborne/Balloon programs..........	4,858	4,800	1,300	5,300
Supporting research and technology	13,870	14,400	3,600	14,700
Data analysis......................	5,000	5,000	1,300	5,000
Skylab data analysis...............	1,400	6,000	1,500	4,000
Space telescope - advanced technological development........	3,000	5,000	2,000	---
LUNAR AND PLANETARY EXPLORATION......	261,200	254,100	67,700	191,100
Viking.............................	89,016	39,500	11,600	24,200
Outer planets missions.............	69,761	82,400	22,100	50,300
Pioneer/Helios.....................	33,642	61,700	16,400	47,400
Mariner-Venus/Mercury..............	5,324	---	---	---
Supporting research and technology/ advanced studies................	11,000	11,000	2,500	11,600
Planetary data analysis............	1,628	1,400	400	2,500
Planetary astronomy................	4,200	4,200	900	4,800
Planetary flight support...........	24,725	29,200	8,700	27,900
Lunar research program.............	21,904	24,700	5,100	22,400
LIFE SCIENCES......................	19,800	20,800	5,200	22,125
Space life sciences................	15,000	16,000	4,300	17,325
Planetary biology..................	3,300	3,300	600	3,300
Planetary quarantine...............	1,500	1,500	300	1,500
TOTAL, SPACE SCIENCE...............	417,315	434,200	116,400	379,025

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Table 4 (Cont'd)

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

SPACE APPLICATIONS

BUDGET PLAN
(Thousands of Dollars)

	FY 1975	FY 1976	Transition Quarter	FY 1977
EARTH RESOURCES DETECTION AND MONITORING	58,687	59,730	13,900	67,300
LANDSAT - 1 & 2	8,700	5,300	---	---
LANDSAT-C	9,000	13,000	3,500	13,500
Applications transfer and demonstration program	8,778	9,300	2,500	14,800
Applications research and technology development and related activities	32,209	32,130	7,900	35,000
Thematic Mapper	---	---	---	4,000
EARTH DYNAMICS MONITORING AND FORECASTING	9,600	8,000	2,200	4,600
LAGEOS	1,300	1,000	300	---
Tectonic plate motion	1,900	2,600	700	1,900
Applications research and technology development and related activities	6,400	4,400	1,200	2,700
OCEAN CONDITION MONITORING AND FORECASTING	15,600	20,800	6,500	30,600
SEASAT-A	8,000	15,000	5,000	25,300
Applications research and technology development and related activities	7,600	5,800	1,500	5,300
ENVIRONMENTAL QUALITY MONITORING	26,400	22,200	9,400	26,100
NIMBUS-G	19,000	13,000	6,700	15,400
Applications research and technology development and related activities	7,400	9,200	2,700	10,700
WEATHER AND CLIMATE OBSERVATION AND FORECASTING	42,073	42,700	9,600	36,300
NIMBUS - 5 & 6	9,300	5,700	---	---
TIROS-N	7,500	8,200	2,100	8,600
GARP	7,200	7,000	2,000	6,000
SMS - 1 & 2	2,100	---	---	---
Severe storm research program	6,973	8,800	2,100	7,100
Applications research and technology development and related activities	9,000	13,000	3,400	14,600
MATERIALS PROCESSING IN SPACE	4,600	5,700	1,200	9,200
SPACE COMMUNICATIONS	12,000	10,000	1,900	10,600
INFORMATION MANAGEMENT	3,200	3,200	800	3,200
APPLICATIONS EXPLORER MISSIONS	2,588	5,900	2,200	10,300
TOTAL, SPACE APPLICATIONS	174,748	178,230	47,700	198,200

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Table 4 (Cont'd)

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

AERONAUTICS AND SPACE TECHNOLOGY

BUDGET PLAN
(Thousands of Dollars)

	FY 1975	FY 1976	Transition Quarter	FY 1977
AERONAUTICAL RESEARCH & TECHNOLOGY	166,400	175,350	43,800	189,100
Research and technology base...	83,472	85,425	21,400	89,700
Systems studies................	2,884	3,096	700	3,000
Systems technology programs....	31,022	43,170	12,300	60,800
Experimental programs..........	49,022	43,659	9,400	35,600
SPACE RESEARCH AND TECHNOLOGY	71,365	74,900	19,300	82,000
Research and technology base...	61,090	61,075	15,700	62,100
Systems studies................	1,600	1,825	400	1,600
Systems technology programs....	1,675	2,200	600	3,100
Experimental programs..........	2,000	3,700	1,100	6,900
Low cost systems program.......	5,000	6,100	1,500	8,300
TOTAL AERONAUTICS AND SPACE TECHNOLOGY..........	237,765	250,250	63,100	271,100

Table 4 (Cont'd)

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

OTHER BUDGET ACTIVITIES

BUDGET PLAN
(Thousands of Dollars)

	FY 1975	FY 1976	Transition Quarter	FY 1977
ENERGY PROGRAMS				
ENERGY TECHNOLOGY APPLICATIONS..	4,435	5,900	1,500	---
TRACKING AND DATA ACQUISITION				
TRACKING AND DATA ACQUISITION	248,000	240,800	63,400	258,000
Operations....................	192,600	193,500	50,100	206,800
Systems implementation........	42,500	38,100	11,000	42,500
Advanced systems..............	9,300	9,200	2,300	8,700
Tracking and data relay satellite system............	3,600	---	---	---
TECHNOLOGY UTILIZATION				
TECHNOLOGY UTILIZATION.........	5,500	7,500	2,000	7,900

Table 4 (Cont'd)

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

RESEARCH PROGRAMS

BUDGET PLAN
(Thousands of Dollars)

	FY 1977
SPACE FLIGHT	-0-
SPACE SCIENCE	320,525
Physics and Astronomy	135,200
Lunar and planetary exploration	163,200
Life sciences	22,125
SPACE APPLICATIONS	45,850
Earth resources detection & monitoring	17,500
Earth dynamics monitoring & forecasting	1,350
Ocean Condition Monitoring & forecasting	2,650
Environmental Quality Monitoring	5,350
Weather & Climate Observation & forecasting	14,400
Materials processing in space	4,600
AERONAUTICS & SPACE TECHNOLOGY	194,300
Aeronautical Research & Technology	125,300
Space Research & Technology	69,000
TOTAL	560,675

Table 5

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

FISCAL YEAR 1977 CONSTRUCTION OF FACILITIES PROGRAM

BUDGET PLAN
(In thousands of Dollars)

PROJECTS BY INSTALLATION	FY 1977
Ames Research Center	4,490
Modification for high enthalpy entry facility..................	1,220
Modification of flight simulator for advanced aircraft........	1,730
Construction of supply support facility......................	1,540
Flight Research Center	750
Construction of addition to flight control facility...........	750
Johnson Space Center	2,800
Construction of addition to lunar sample curatorial facility..	2,800
Kennedy Space Center	2,805
Construction of airlock to spin test facility.................	360
Modifications for utility control system.....................	2,445
Langley Research Center	6,185
Construction of addition for aeroelastic model laboratory.....	730
Construction of data reduction center annex..................	2,970
Construction of refuse-fired steam generating facility........	2,485
Lewis Research Center	2,170
Modification of refrigeration system, electric propulsion laboratory..................................	680
Rehabilitation of combustion air drying system, engine research building.................................	1,490
Large Aeronautical Facility	25,000
Construction of national transonic facility (LaRC)............	25,000
Space Shuttle Facilities at Various Locations as Follows:	39,825
Construction of orbiter processing facility (KSC)............	3,750
Modifications to launch complex 39 (KSC).....................	19,855
Modifications for solid rocket booster processing facilities (KSC)..	9,700
Construction of shuttle/carrier aircraft mating facility (KSC)	2,050
Modifications for crew training facilities (JSC).............	780
Rehabilitation and modification of shuttle facilities, at various locations....................................	1,760
Modification of manufacturing and final assembly facilities for external tanks, (MAF)........................	1,930

Table 6

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

FISCAL YEAR 1977 CONSTRUCTION OF FACILITIES PROGRAM

BUDGET PLAN
(In thousands of Dollars)

PROJECTS BY INSTALLATION	FY 1977
Space Shuttle Payload Facilities at Various Locations as Follows:	4,340
Modifications to operations and checkout building for spacelab (KSC)	3,570
Modifications and addition for shuttle payload development (GSFC)	770
Rehabilitation and Modification of Facilities at Various Locations, Not in Excess of $500,000 Per Project	17,875
Minor Construction of New Facilities and Additions to Existing Facilities at Various Locations, Not in Excess of $250,000 Per Project	5,125
Facility Planning and Design	12,655
TOTAL PLAN	124,020

Table 5 (Cont'd)

Chapter 4

PROCUREMENT/CONTRACTING

It was assumed from the beginning that much of NASA's work would be done by contract, especially in hardware development. Since NASA's mission necessitates large scale contracting, this area is one of NASA's basic administrative problems.

NASA is an R&D agency which requires that most of the goods and services that it procures by contract are unique and not readily available from commercial sources. The variety of equipment and services procured by NASA include: launch vehicles, small electronic instruments for spacecraft, satellites, feasibility studies and investigations, construction of research facilities and administrative supplies and equipment.

The Space Act granted NASA broad powers to develop, construct, test and operate space vehicles and to enter into contracts for the conduct of work with individuals, corporations, Government agencies and others. It also extended to NASA the procurement authority contained in the Armed Services Procurement Act of 1947. This relates to the procedures governing contracts made by DOD. Therefore, NASA and

DOD are governed by the same procurement statutes and deal, to a considerable extent, with the same segment of industry. The major steps in the procurement process are described below.

Once a project has been approved and a decision made as to the degree of external participation, the responsible organizational unit prepares a procurement request (PR). The PR, after approval by the proper operating officials, becomes the basic working document for the procurement specialist. The PR includes a description of what is wanted and additional information as needed (suggested suppliers, security classification, etc.).

On the basis of the PR and other available information, the procurement specialist draws up a procurement plan. This plan outlines in detail each subsequent step to be taken to carry out the procurement action. It includes a description of the items to be procured, a list of all known sources, a time schedule for completing each major phase of the action, the recommended type of contract to be used, and special provisions to be included in the contract. If the items to be procured can be clearly and completely defined in specifications and drawings, formal advertising for competitive bids is possible. If the items cannot be well defined (and most R&D work cannot), the negotiation route must be taken, whereby negotiations with potential suppliers are conducted on the basis of competitive technical and business proposals submitted to NASA. The "formal advertising" route usually results in a fixed-price contract whereas the "negotiation route" usually involves a cost-reinbursement contract - normally cost-plus-a-fixed-fee (CPFF) or cost-plus-an-incentive-fee (CPIF). When the procurement plan has been approved by the proper authorities, the stage is set for solicitation.

At this stage, an attempt is made to keep things as competitive as possible. When formal advertising is used, the procurement action is publicized as widely as possible and an "Invitation for Bid" (IFB) is sent to each interested supplier. The IFB contains all information needed to prepare a bid.

Negotiation is more complicated. An instrument called a "Request for Proposal" (RFP) is used instead of an IFB. Since a proposal is more complicated and expensive to prepare than a bid, NASA attempts to limit the sending of RFP's to parties known to be qualified. This necessitates a screening process, which may be done informally through letters and telephone calls or formally through a "preproposal conference" held with interested parties. On the basis of the screening, RFP's are sent to firms considered to have the required experience, facilities and capabilities. A firm may submit a proposal even if it does not initially receive an RFP. All larger RFP's are announced in the Department of Commerce's Business Daily and thus a firm can request them.

When formal advertising is used, it is necessary to make sure that the low bidder is responsible and that his bid meets all requirements.

When negotiation is used, a much more elaborate evaluation process is necessary, since cost figures are only one factor to be considered. Proposals are usually evaluated from three angles - the quality of the proposal (design, cost, schedules, etc.); the technical competence of the proposer (personnel, facilities, experience); and the managerial competence of the proposer (reporting system, accounting system, etc.). The RFP includes the criteria on which the evaluation is made. Administrative and legal personnel, as well as technical personnel, participate in proposal evaluation.

In the case of formal advertising, a standard-type contract is awarded to the lowest responsible and responsive bidder. When negotiation is used, a decision is made, based on the evaluation described above, on the supplier to do the work. After selection, negotiations are begun to iron out the details of the contract. Since cost-type contracts are used in most cases, problems of clarifying costs and determining the fee must be solved. When both sides agree, the actual contract award is made.

The award of a contract is only part of the overall procurement process. What follows may be even more significant. It is true that the contractor has primary responsibility for performance and, for routine procurements, contract administration may only involve taking delivery of the goods or services. In R&D contracting, however, numerous interim problems arise in which NASA has a vital interest. In such cases, reviewing and evaluating the contractor's progress is very important and may become a specialty in itself. Elaborate reporting techniques have been developed which sometimes reveal the need for NASA to render technical or administrative assistance to the contractor. NASA may approve certain contractor actions which involve changes in costs. In certain cases, the contract may have to be modified or terminated. Contract administration involves NASA operating technicians, procurement specialists, and people from such activities as safety, reporting and security.

In order to provide the degree of flexibility which is essential to the effective performance of basic research, most Government agencies, NASA included, use the grant as the preferred procurement instrument for such work. NASA's authority to award grants is limited by Public Law 85-934 to nonprofit institutions of higher education and nonprofit organizations whose primary purpose is the conduct of scientific research.

NASA has developed a unique system relative to grant issuance. It is a step funding grant program. Under this program, NASA may issue a nonrenewable five year grant for which funding, during each of the final three years, is reduced by one-third. Through the use of this program, grant duration and agency obligation is limited to a reasonable period - five years. Should the research conducted under the grant prove worthwhile continuing, the university has the opportunity to develop other sources of funding. [14]

Chapter 5

THE FORMAL PROJECT REVIEW AND APPROVAL SYSTEM [15, 16]

The Project Approval Document (PAD) constitutes the principal element in the agency-wide review and approval system. No project has operational status until the Administrator approves the PAD. It contains a broad description of the project, what it is to accomplish, specific technical goals, how it fits into NASA's program in general, how it will be organized and managed, schedule and principal milestones for measuring progress, the estimated budget for its entire life cycle, and facilities and personnel required. The PAD is the responsibility of the program office concerned (e. g., OSSA or OART), but the planning, data collecting and development of the PAD usually are the result of a joint venture between the Headquarters division having substantive cognizance (e. g., OSSA's Physics and Astronomy Division) and the field installation which as been conducting preliminary studies and to which it is proposed to assign the project (e. g., Goddard Space Flight Center). The PAD receives a technical and management review by both program and functional offices in NASA Headquarters. After approval by the Administrator, it constitutes a "contract" between NASA executive management and the initiating program office

(e. g. , OSSA) on the technical objectives, schedule, financial resources and management plan of the project.

The Project Plan is a much more detailed version of the PAD. It is prepared by the field installation (usually the project manager and his staff) assigned the project . for approval by the Associate Administrator (e. g. , OSSA). A draft Project Plan usually is the basis for writing the PAD. The Project Plan is reviewed within the field installation responsible for the project, as it is in the Headquarters program office to which it is directed. Upon approval by the Associate Administrator, the Project Plan constitutes the "contract" between NASA Headquarters (e. g. , OSSA) and the field installation (e. g. , Goddard) for the project.

During the course of a project, its progress is monitored at both the field installation and NASA Headquarters; the PAD and the Project Plan are used as bases for assessment. Whenever some problem necessitates a change in either the PAD or the Project Plan, that change must be reviewed and approved by the same process used in establishing the project.

At critical points during the life of a project, detailed technical reviews are conducted to expose any problems or potential malfunctions before committing the project to the next step. These reviews draw on the principal managers directly involved in the project from Headquarters (the program manager); the field installation (the project manager and his principal assistants); the contractor (his project manager and assistants); and technical specialists in testing, reliability, quality control, electronics, mechanics, thermal systems, propulsion systems, and communications from outside the project organization; or other specialists pertinent to the particular project and its stage of development at the time of the review. Here the Project Plan, test results , and experimental data will be the principal points of reference. Where problems are revealed, it becomes the project manager's responsibility to demonstrate to his field installation management and the program manager that the problems are being solved effectively.

Chapter 6

MANAGEMENT OF NASA PROGRAMS

Most NASA projects follow either a matrix or project type of organization. Under a matrix organization, employees may be assigned temporarily to a project, but they remain on the rolls of their parent organization and are under that organization's jurisdiction for merit reviews, promotions and similar formal supervisory action. They may be physically located within their parent organization rather than in the project location. The matrix organization has the advantages of more efficient use of specialized talent, flexibility in applying that talent to the most urgent problems, and a broader perspective for supervising and evaluating technical personnel. Because the project manager lacks direct, formal control over many of the team members, managers tend to consider the matrix less responsive than project organization. The matrix does suffer from problems associated with dual allegiance and a formally unsystematic or cumbersome authority structure. This type of project organization usually is preferred by the senior management of agencies or companies where several major projects are underway at the same time.[17] The matrix is the preferred project organization in NASA.

In its purest form, a project organization gives the project manager direct control and full authority over all of the people assigned to the project. This form tends to be favored by managers of large projects. It permits ease of control, clear location of responsibility, quick reaction from the project team, and a simple pattern of communications. It is less flexible and not so economical in utilizing personnel as is the matrix organization, because it may prove difficult organizationally to transfer a specialist to the project for only that period of time when he is most needed. Project organization also tends to isolate the project group from the rest of the installation, reducing technical interchange and, possibly, technical innovation.

The NASA concept of project management is based upon a philosophy of integrating the technical and managerial competence of industry, NASA laboratories, and university scientists within a system that could best be called one of participative responsibility. Most NASA flight projects are of such scope that they constitute national projects, and this requires that national competence, irrespective of its location, be applied.[18]

NASA senior leadership recognized the need to improve upon the prevailing style of project management most typically found in major engineering development programs throughout the 1950s. That approach was characterized as writing specifications for the development program, letting the contract, and depending largely upon the contractors for the resulting product. The weakness in this system was that it did not provide for satisfactory, positive intervention by the customer in the solution of and decision on the technical problems which inevitably arise in a development program. Too often government project managers lacked the supporting organizational system and in-house technical support necessary to manage contractors most effectively.

The NASA project management concept is that no single company has all of the skills and experience required for the execution of a large space flight project. Therefore, although it relies predominantly upon the aerospace industry to build, integrate, and test flight hardware, NASA uses its in-house management and technical competence - to monitor and to work with the contractor. NASA retains the authority and the means for tapping a much wider variety of technical competence to overcome problems confronting a contractor on a project.

For example, NASA can bring in experts from its field installations, from universities, or from other government laboratories to help solve a problem. The concept is to manage the project on a teamwork basis in order to avoid unnecessary delays that might be occasioned by working across organizational boundaries separating public, private and semi-private organizations. The same practice applies to NASA's field installations and project groups - organizational boundaries are not to interfere with the application of needed talent.

This concept, requiring teamwork and central control but decentralized project execution, respects the semi-autonomous status of the NASA field installations which are the locus of most of NASA's technical talent. It requires a different organizational structure from that of previous project management. In NASA terminology, a program is a related series of undertakings which continues over a period of time - normally years - and which is designed to accomplish a broad scientific or technical goal in NASA's long-range plan, such as Lunar and Planetary Exploration. Program responsibility is assigned to the appropriate program office, such as OART or OSSA, within NASA Headquarters.

A project is an undertaking with a scheduled beginning and ending, within a program. It normally involves the construction and operations of one or more aeronautical or space vehicles, and necessary ground support in order to accomplish a scientific or technical objective; or the design, development and demonstration of major advanced hardware items; or the design, construction and operation of a new launch vehicle.[19]

NASA has identified the program managers role vs. the project manager's role as follows:[20]

> A program manager is the senior NASA staff official who serves as the focal point of all NASA Headquarters activity bearing directly upon those projects and other activities which his program comprises. He is responsible for developing and administering the Headquarters guidelines and controls under which those projects are conducted, including keeping the basic organizational capabilities healthy. He is not to push his projects at the expense of NASA's broader goals. On large space flight projects, the program manager frequently has cognizance over only one project, such as Nimbus, the Applications Technology Satellite, or Surveyor.

> A project manager is the senior official at the NASA field installation exclusively responsible for the execution of a project within guidelines and controls prescribed by NASA Headquarters and his field installation's management. The project manager is the focal point of all field installation activity bearing directly on his project. He carries out these responsibilities within his delegated authority in the name of the field installation director.

In essence, the project manager is responsible for the day-to-day supervision and the execution of the project as carried out by industrial contractors, NASA and other government laboratories, and university experimenters. The program manager is responsible for resource allocation within NASA Headquarters; preparing testimony and justification for Presidential and Congressional authorization; working with other government and non-government organizations interested in or participating in the project; and monitoring the project execution, to relate it to NASA as a whole, and to control significant variations from the Headquarters' approved Project Plan.

Chapter 7

INNOVATION

In order for an organization to be innovative - conduct successful research and development - somewhere in that organization there must exist a "Product or Project Champion." This individual must be ready to stake his reputation and position to enhance the accomplishment of the project. The higher in the organization this individual sits, the more likely will the necessary resources to conduct the given project be made available.[21]

NASA's most costly project was the Apollo Program. It was a national goal to put a man on the moon by 1970. The project champion for this program was President Kennedy. Using his leadership, political ability, influence and position within the organization (the United States Government), the President made sure that the resources to complete this endeavor successfully were made available. Programs of lesser national importance, scientific importance and lower cost, require project champions of lower rank, but in order to achieve innovation the project champion must exist in a management position.

NASA tends to manage its science in this manner. NASA programs which emerge from within the organization tend to develop from ideas originated by scientists or engineers at the various NASA Centers. The scientist must find a project champion either within his Center or at NASA Headquarters. The necessary position of the project champion within the management hierarchy is a function of the cost of the scientist's project. The normal road in the pursuit of the project champion is up each step of the management ladder one rung at a time with the scientist or engineer seeking the blessing of his superiors until he discovers the individual who is not only willing to bless his idea but to help the scientist obtain the financial backing he requires.

Sometimes the scientist may skip some of the ladder's rungs in seeking his champion. He may even go directly to Headquarters in his quest. This is not usual however, but is a function of the position within the Center organization the scientist holds.

This system is very similar to the system which exists at innovative companies in industry.

Should a company, federal agency, university, state or local agency, or any other outside organization, desire NASA to include one of its ideas in the NASA budget, the outside organization must perform the same quest within NASA as does the NASA scientist.

It is true that the outside organization can submit an unsolicited proposal containing its idea through official NASA procurement channels; however, chances that the proposal will be funded are dim at best.

Through its knowledge of NASA and NASA personnel, if the outside organization finds a project champion and then submits an unsolicited proposal, chances of the proposal being funded by NASA are at a minimum, much brighter.

Typically, the largest cost in the accomplishment of a NASA program is the cost of the launch. Launch cost includes the cost of the launch vehicle. This cost can amount to as much as $10 to $15 million. Another cost which can be in the same ballpark is the cost of the mission vehicle, e. g, satellite, landing vehicle, deep space vehicle, etc. If every project that NASA performed had to bear the costs of launch and the project vehicle, NASA would carry out very few in space projects.

Each project that NASA conducts contains one or two major missions or experiments. The approximate equipment weight for these experiments, including the vehicle, is determined. The required launch vehicle from the NASA inventory, e. g., Saturn, Titan, Delta, Scout, Atlas-Centaur, etc., necessary to lift the mission equipment weight into space, is selected. The launch vehicle will have lifting capacity in excess of that required for the major mission. This excess lifting capacity permits NASA to include the equipment required to conduct additional missions and experiments which are related to the major mission contained in the particular project. In some cases the additional experiments can number in the hundreds. In this manner, the project costs can be amortized over a large number of experiments rather than only a few and NASA, in effect, obtains more science for its money, lowering the cost of innovation.

Chapter 8

PATENTS

The organic act which established NASA contains special patent provisions concerning inventions made by NASA contractors. Section 305 of the National Aeronautics and Space Act of 1958 establishes:

1. standards which shall be used in determining the circumstances under which inventions shall be deemed Government sponsored and thus Government owned;
2. requirements for acquiring the full disclosure of inventions;
3. procedures for enforcement of the Government rights, as well as for administrative appeal; and
4. authority in the Administrator to waive the rights of the United States respecting any invention made in the performance of work under a NASA contract whenever the interests of the United States will be served thereby, and the grant licenses for the practice of any invention on which NASA holds a patent on behalf of the United States Government.

This section of the act has been implemented through the issuance of regulations governing the licensing and the waiver of rights of the United States to inventions, as well as regulations which set forth policies, instructions and contract clauses prescribed for use in NASA contracts.

It is NASA's policy, with respect to a procurement likely to infringe on a valid patent, to enter into a precontract license agreement with the patent holder. This encourages privately financed research.

The same NASA Act authorizes the Administrator to make awards for scientific or technical contributions having significant value in the conduct of aeronautical or space activities. Such contributions would include innovations or inventions which have been used with proven value, many of which come into being during the performance of NASA contracts.[22]

The NASA patent policy described in "4." above, and the ability of the Administrator to make awards for scientific contributions, are significantly different from the policies of many other Federal agencies. The DOD policy on patents requires that inventions made in the performance of a DOD contract become the property of the Government. Since NASA and the DOD contracting policies and procedures are so similar in other respects, it is unusual for their policy to differ so greatly in the area of patents. When the National Aeronautics and Space Act of 1958 legislation was drafted, significant objections were rendered by DOD on this point.[23] It was hoped, when the legislation was proposed, this liberal patent policy would tend to increase the probability of innovation during the conduct of a NASA contract.

Chapter 9

UNSOLICITED PROPOSALS

An important method of doing business with NASA is through the submission of relevant new ideas and concepts in the form of unsolicited proposals. In general, most appropriate for the unsolicited approach is research of a fundamental nature - that which bears potential for advancing the state-of-the-art in a particular area, contributes to knowledge of a specific phenomenon, or provides fundamental advances in engineering or the sciences. In addition, proposals may define problems and present possible solutions to the problems, developmental or otherwise, which are within NASA's areas of concern.

Familiarity with NASA programs and projects through contacts with NASA's technical personnel may reveal the existence of a community of interest. If such mutual interest exists, submitting an unsolicited proposal may be appropriate. However, the existence of such mutual interest does not, in itself, commit NASA to the support of any resulting unsolicited proposal. NASA considers such additional factors as the technical merits of the proposal, the availability of funds, and the relative priority of the project as compared with other alternatives under consideration.

Though oriented more toward NASA relationships with the university community, it is also applicable to industrial, commercial and other nonacedemic organizations.[24]

The unsolicited proposal approach is another manner in which NASA tries to enhance innovation.

Chapter 10

TECHNOLOGY TRANSFER

What is Technology Transfer with regard to research and development? It is many things to many people. Some definitions are: the multi-lateral flow of information and techniques across the boundaries of the sciences, technology and the practical world; transferring research results to operations; accelerating the application of research and exploratory development results to industrial application; science and technology transfer to the would-be user at the earliest practicable date and in a language he can understand; the process of matching solutions in the form of existing science and engineering knowledge to problems in commerce or public programs.[25]

Based upon these definitions, the NASA technology transfer program is extensive. At NASA the program is called Technology Utilization. Each NASA Center has a Technology Utilization Office, as does NASA Headquarters. The space program has been extremely costly in terms of dollars since NASA's establishment. One of the major tools NASA employs in order to help justify this cost, is the dissemination of information concerning innovations derived from the space program, which apply to solving problems in other areas. The National Aeronautics and Space Act of 1958 in

Title II Section 203 sets as one of NASA's responsibilities: "to widely disseminate information about aeronautical and space activities."

NASA shares its research with others interested in advancing the state-of-the-art. Publication in NASA's technical series or in technical journals is encouraged.

The Scientific and Technical Information Office, NASA Headquarters, in addition to its other activities in the information field, is responsible for collecting, abstracting, announcing and disseminating the reports resulting from the work performed by NASA and its contractors, subcontractors and grantees. It is also responsible for locating, acquiring and disseminating to the NASA community, scientific and technical information originating outside the NASA complex.

The Technology Utilization Program makes available to industrial firms and other interested groups, the results of NASA-sponsored research and development in several ways: NASA Tech Briefs are single-page announcments of innovations, improvements and other types of discrete advances in the state-of-the-art; Technology Utilization Reports describe innovations of special significance or complexity; Technology Utilization Surveys consolidate the results of NASA-sponsored research and development which advanced whole areas of technology; Research and Technology Operating Plan Summary (RTOP) is an annual compilation of NASA-funded research and technology programs in abstract form. It is designed to facilitate communications and coordination among technical personnel in government, industry and universities. The RTOP Summary briefly describes NASA's R&D objectives, identifies the installation of primary interest and provides a point of contact for technical information.

As the Office of Technology Utilization is responsible for the dissemination of information derived from the space program, the Office of Applications is responsible for carrying out programs which demonstrate the application of space related capabilities to the practical benefit of mankind.

The major on-going program presently underway in the Office of Applications is the Applications Transfer and Demonstration Program. This program constitutes NASA's major effort to involve user organizations in applications of remote sensing so as to accelerate the adoption by the user community of those techniques which are valuable in carrying out their operational resources management missions. The great majority of these projects called Applications Systems Verification Tests (ASVT), are relatively large scale cooperative projects that NASA enters into by written agreement with other federal agencies and state governments, as well as with regional and private groups, to develop and demonstrate over a period of two or three years the operational utility of remotely sensed data to the solution of resource management problems.

It would be instructive here to give some specific examples of ASVT projects.[26]

NASA is collaborating with the Department of Agriculture (USDA) and the National Oceanographic & Atmospheric Administration (NOAA) in the Large Area Crop Inventory Experiment (LACIE) to develop techniques to monitor and predict wheat production on a global basis. The specific objective of LACIE is to provide such forecasts with an improvement over existing methods in terms of accuracy, timeliness and objectivity.

NASA is working with the U.S. Corps of Engineers, and the states of Mississippi and Georgia on the Louisiana Environmental Information System ASVT and the Mississippi Natural Resources Inventory ASVT, which provide mapping and monitoring activities through the use of the LANDSAT Satellite.

In a cooperative program with EPA, NASA is developing the operational capability to monitor the effects of surface mining and power plant setting in the western states using aircraft and spacecraft techniques.

The Snow Mapping ASVT in the far western states is to demonstrate watershed runoff prediction using remotely sensed data with near real-time computation techniques.

The Icewarm ASVT, in cooperation with the U.S. Coast Guard, assists Great Lakes shippers in extending the winter shipping season by using remotely sensed data from aircraft to monitor ice conditions.

New ASVT projects scheduled to begin during FY 1977 involve Water Management and Control, Wildland Vegetation Inventory, Pacific Northwest Resources Inventory and Eastern Regional Surface Mining.

Presently under development by NASA is the Thematic Mapper. This device will extend the LACIE Project by providing greater resolution of crops and the facility to discern different types of vegetation. The improved resolution should be useful in areas other than agriculture. These uses include urban land use patterns, the extent of flood damage, changes in forest cover, mapping of fault lines and alteration zones associated with potential mineral deposits.

NASA's program in materials processing in space is directed toward stimulating industry and other organizations to sponsor their own space activities in materials science and technology. It is hoped that this research and development will lead to commercial manufacturing operations.

Orbiting Geophysical Observatory (OGO) experiments determined that observations made at satellite altitudes could be related to the magnetic field at the surface of the earth. The U.S. Geological Survey (USGS) has a requirement to update the magnetic field model of the earth every ten years and to update magnetic field charts used for navigation every five years. When used in conjunction with gravity field variations, magnetic field variations form an important tool in mineral and petrolium exploration.

Presently the USGS obtains magnetic field data using aircraft and ground measurements. Consequently the existing information is limited to areas over which such surveys can be performed. NASA has developed the Magnetic Field Satellite (MAGSAT) to enhance the gathering of magnetic field data, in order to permit USGS to more easily and rapidly perform its magnetic field modeling and charting functions.

In the communications area, intercontinental telephone and television transmission have become commercial realities through NASA experimentation over the years. This year NASA launched the Communications Technology Satellite (CTS), which has as its mission providing operational television broadcast direct to individual receivers at a frequency band allocated specifically for that purpose. This program is a joint effort with Canada.

Through the use of its Applications Technology Satellites, NASA in cooperation with the European Space Agency (ESA) has developed the Position Location and Aircraft Communications Equipment (PLACE). This equipment permits ground controllers to know the current location of and communicate with commercial airliners while the planes are over the open ocean. This knowledge permits the controllers to decrease separation requirements between aircraft and to more easily locate aircraft in the event of an over-ocean crash. Based upon the results of the

PLACE Program, the FAA in conjunction with the ESA member countries and Canada is developing an operational system, the Aeronautical Satellite (AEROSAT).

Although the Office of Applications is responsible for carrying out programs which demonstrate the application of space related capabilities to the practical benefit of mankind, an examination of Table 7 will indicate that it is by no means the only area in which technology transfer is investigated. Spinoff benefits have come from all areas of NASA research and technology. To put the NASA technology transfer program into perspective with regard to economic benefits derived from NASA R&D, The Morganstern Study[27] indicates that in the areas of: gas turbines in electric power generation; integrated circuits in consumer products; space derived insulation for cryogenics; and computerized structural analysis; a total of $6.9 billion in benefits have been achieved. Further, the Chase Econometrics Study[28] concludes: each dollar invested returns fourteen dollars to the economy over a ten year period through increased productivity alone.

MANUFACTURING/CONSUMER PRODUCTS/RETAILING/CONSTRUCTION

Battery Powered Hand Tools - Commercialized by Black & Decker into Line of Six Cordless Power Tools for Lawns and Gardens

Aluminized Mylar Developed for ECHO Satellite - Adapted for Use in Making Blankets, Coats, Ski Parkas, Sleeping Bags, and Life Raft Canopy and Various Emergency Reserve Products

Apollo Guidance Computer Software - Used to Develop Computerized Retail Sales System - Used by Montgomery Wards, May Co., Neiman-Marcus, J.C. Penney, Rich's and Many More

Highly Reliable Flashlight Switch - Developed for Manned Spacecraft - Now Commercialized

Composite Materials Data - Used by Babcock & Wilcox C. to Develop Products Used in Business Machines and Golf Club Shafts

Management Method - Used by Upjohn Co. to Save Substantial Man-Hours in Management of Research Programs

Safety Yoke for Construction Workers - Developed for Kennedy Space Center Workers, Insurance Company now Advises Use to Reduce Industrial Accidents

Multiplexer Circuit for Saturn Rocket - Used in Most U.S. Textile Weaving Mills and in Many Foreign Countries

Dry Lubricant Coating Processes - Used by over 600 Manufacturers including GE, IBM, RCA, Westinghouse, and ITT

Intumescent Fire Retardant Coatings - Used to Coat Fuel Hoses, Fuel Tanks, and Engine Compartments on Pleasure Boats

Ultrasonic Nondestructive Testing Techniques - Used for Quality Control Inspection in Aircraft, Steel, Railroad, and Automotive Industries

Table 7 - Selected NASA Technology Transfer Benefits [29]

MANUFACTURING/CONSUMER PRODUCTS/RETAILING/CONSTRUCTION (cont.)

Surface Finishing Method for Nickel Alloys - Used by Westinghouse to Finish Components for Gas Turbine Electric Generators

Fluidic Controls - Used to Control Automatic Metalworking Lathes

Lubricant Deposition Process - Used for Many Products - Film Coating, and Brushes for Electric Motors Used in Car Air Conditioners, Vacuum Cleaners, etc.

Specification Guidelines for Hybrid Microcircuits - Used by Bell & Howell

Fracture Toughness Tests - Used by Aluminum Company of America to Provide Fracture Toughness Guarantee for High Strength Alloy Products

Weld Strength Prediction Method - Used by Kodak Chemical Plant to Eliminate Hazard of Rupturing Pipes that Contain Chemicals

Mass Flowmeters for Low Gas Flow - Used Extensively by Manufacturers in U.S., Europe, and Japan for Assorted Applications

Technique for Reducing Noise in Radio Amplifiers - Used by GTE and Sylvania in High Sensitivity - Low Noise Receivers

Apollo Program Management Techiniques - Used by Rockwell International Standard Division, Major Producers of Truck and Bus Components

Spun Metal Fibers for Web Filters - Developed by Hydraulic Research and Manufacturing Co. for Apollo - Commercially Available for Many Different Application

Heat Pipe Technology - Air-O-Space Heater by Isothermics, Inc. Recovers Waste Heat from Furnace Flue Gas - Increases Heat Efficiency 8-10%

Table 7 - Selected NASA Technology Transfer Benefits [29]

MANUFACTURING/CONSUMER PRODUCTS/RETAILING/CONSTRUCTION (cont.)

Rogallo Airfoil Design - Used as a Basis for Design of Hang Gliders

Anti-Fog Compound - Used for Fire Fighters Face Shields, Air Masks, Ski Goggles, Eyeglasses, etc.

Chlorate Candle Oxygen Supply - Technology Used to Develop Portable Welding Torch

Quartz Crystal Oscillator for Apollo Central Timing Equipment - Used in Clocks and Watches - Accuracy to Within One Minute per Year

Combustion Analysis Computer Programs - Used by Power Companies to Design Firing Modifications for Power Plant Fossil-Fuel Boilers

Digital Color Television Display - Used by Electric Power Companies as Part of Dispatch Computer System to Reduce Possibilities of Major Blackouts

Atlas Centaur Rocket Control System - Design Principles Used in Control System for High Temperature Gas-Cooled Nuclear Reactors

Apollo Program Quality Assurance Specifications - Used by GE to Develop a Nuclear Quality Assurance Consulting Service for Utility Companies

NASA Structural Analysis Program - Used for Designing Nuclear Power Plant that will Float Offshore

Fuel Cell Technology - NASA Needs have Spurred Private Research into Fuel Cell Development

Fusion Welding Workmanship Standards - Used to Develop Weld Methods for the Foster Joseph Sayers Dam Project in Pennsylvania

Heat Shield Coating for Reentry Vehicles - NASA Requirements have Encouraged Private Development of Heat Resistant Coatings for Construction Materials

Instrumentation Electronics for Saturn Rocket - Used to Design a Ground Fault Interrupter That Will Fit Inside a Standard Home Circuit Breaker

Computer Program Translating Guide - Used to Design Foundations for Buildings Such as the Sears Building in Chicago

Table 7 - Selected NASA Technology Transfer Benefits[29]

MANUFACTURING/CONSUMER PRODUCTS/RETAILING/CONSTRUCTION (cont.)

Deployable Lattice Column - Used in Demolition Industry for Controlled Removal of Buildings and Bridges

Cryogenic Data Handbook - Used to Design Low Temperature Construction Projects Such as LNG Storage Facilities and Refrigeration Systems for Freezing Loose Ground in Preparation for Excavation

Fiberglass Fabric - Used for Nonflammable Clothing and Structures

Geodesic Structure Design Program - Used to Design Commercial Geodesic Structures

NASA Program Evaluation and Review Technique - Used for Project Scheduling in Construction and Other Industries

Table 7 - Selected NASA Technology Transfer Benefits [29]

PETROLEUM AND GAS

Heat Pipe Technology Developed for Skylab, Shuttle, and Unmanned Satellites - Used in the Construction of the Alaskan Pipeline

Infrared Scanner and Television Display - Used for Maintenance Inspections at Petrochemical Plants and Refineries

Hot Tapping Method for Pipes - Used by American Oil Co. to Repair Pipes and Valve Leaks

Multiplexer Circuit for Saturn Rocket - Used for Remote Data Acquisition and Control Systems for Oil and Gas Pipelines and Oil Field Production Equipment

Apollo Guidance Computer Software - Adopted for Use in Control Systems for Oil Field Production and Oil and Gas Pipelines. Used by Over 3 Dozen Major Oil and Gas Companies

Reliability and Quality Assurance Methods - Basis for Improved Assurance by Federal Government and Industry that Offshore Oil and Gas Will be Produced Safely and with Minimal Pollution

Cryogenic Transfer System Cooldown for Nuclear Rocket Engine - Used by Chicago Bridge and Iron Co. to Design Piping Systems at Most Large LNG Import Terminals in U.S.

Nondestructive Testing Training Manuals - Used by Mobil to Train New Employees in Maintenance Inspection Procedures for Refineries

Lubrication Handbook - Used to Solve Special Lubrication Problems - All Major Oil Companies Have Ordered at Least One

Combustion Analysis Computer - Used by Phillips to Generate Chemical Equilibrium Composition Tables for All Combustion Research Projects

Table 7 - Selected NASA Technology Transfer Benefits [29]

PETROLEUM AND GAS (cont'd)

Systems Safety Technology - Used to Prepare Successful Proposal for the Department of Interior for Alaskan Pipeline Safety Project Resulting in $18 Million Contract Award

Computer Program Translating Guide - Used by Shell to Convert Approximately 500 Programs for New Computer and by Mobil Oil for Same Purpose

Table 7 - Selected NASA Technology Transfer Benefits [29]

TRANSPORTATION

Highway Grooving for Airport Runways and Highways - Greatly Reduces Accident Rate on Wet Highways

Apollo Guidance Computer Software Used by Los Angeles to Control Traffic Lights on 9 Mile Square South Bay Area

NASTRAN (NASA Structural Analysis Program) Used by Ford and GM for Design Analysis - Used by Pullman Standard in Design of New Railroad Cars

Saturn 1/1B System Development Breadboard Facility - Used by Chrysler to Develop New Products and New Car & Truck Testing

Combustion Analysis Computer Program - Used by GM in Combustion Research of Auto and Aircraft Engines

Statistical Procedures to Analyze Noise Test Data from Automobile Steering Systems

Tires for Apollo 14 Mobile Equipment Transporter - Goodyear Uses Some Rubber Compounds in New Automobile Snow Tires that were Developed for MET

Ultrasonic Nondestructive Testing Techniques - Used to Detect Flows in Railroad Tracks

Apollo Guidance Computer - Being Tested by Southern Pacific Railroad for Control of Rail Switches and Train Movement

Dynamic and Static Modeling Techniques - Used by Martin Marietta Corporation to Develop Dynamic Model for Railroad Hopper Cars

Videotape Storage and Retrieval System - Used by Southern Pacific Railroad - One Tape Stores Records from 10 four-drawer File Cabinets

Arc Suppression Techniques Evaluation - Used in Design of Rapid Transit Switch Control Products

Table - Selected NASA Technology Transfer Benefits [29]

TRANSPORTATION (cont.)

Liquid Penetration Nondestructive Testing Training Manuals - Used to Train and Certify Production Line Inspectors at Beech Aircraft Corp.

Inertial Navigation Equipment for Apollo and Lunar Module - Now Installed in Many Commercial Aircraft

Apollo Guidance Computer - Used by Nation-wide Travel Industry in Checking Credit Cards, Personal Checks, Airline Tickets, and Other Non-cash Payments

Friction Characteristics of Graphite and Graphite-Metal - Used by B.F. Goodrich and Others in Company-Sponsored R&D Projects Related to Aircraft Brakes and Gas Turbine Engines

Inflatable/Nontippable Life Raft for Recovery of Astronauts Now Available as Survival Equipment for Pleasure Boats and Aircraft

Cooling System for Astronauts Space Suits - Adapted for Use as Galley Refrigeration System for Commercial Aircraft

Table 7 - Selected NASA Technology Transfer Benefits [29]

GOVERNMENT AND LAW ENFORCEMENT

Saturn Rocket Systems Development Breadboard Facility - Used to Design Memory System for New Post Office Automated Parcel Sorting Equipment

Slidell Computer Complex - Used by National Weather Service to Forecast Flow of Rivers in Five State Area

Apollo Management Control Room - Used to Design Management Control Rooms for Other Government Projects

Space Simulation Chamber - Used to Restore Water-Damaged Records with Heating/Freeze Drying Process

Fireman's Breather Apparatus - To Be Commercially Available in Late 1975 - Features Reduced Weight, Increased Duration, and Simplified Harness. Also Helmet/Mask Assembly and Air Depletion Warning Device are Improved

Flammability Tests of Home Furnishings - Used by U.S. Department of Agriculture to Design Better Fire Tests

Scientific and Technical Information Management System - Primary Storing and Retrieving System for the National Criminal Justice Reference Service

Videotape Storage and Retrieval System - Used by Law Enforcement Agencies Including the Royal Canadian Mounted Police

Systems Analysis and Computer Modeling - Used to Develop City-Wide Emergency Command and Control Commucnications System

High Intensity Arc Radiation Source - Adapted for Use as a Portable High Intensity Spotlight - Used by Police and Fire Department - Can Operate from Automobile Cigarette Lighter - Brighter than Headlights of 50 Automobiles

Table 7 - Selected NASA Technology Transfer Benefits [29]

HEALTH SERVICES/REHABILITATION

Rechargeable Heart Pacemakers Using Nickel-Cadmium Battery Technology

Composite Materials Used for Lightweight Limb Braces

Open-Celled Polyurethane-Silicone Plastic Foam

Mobile Automated Metobolic Analyzer Used to Measure Energy Expended by Orthotic-Equipped Patients

Mercury-Zinc Battery Technology Used for Heart Pacemaker

Artificial Hand with Trigger Finger

Control Switch Operated by Eye Movement - Allows Paralyzed Patient to Control TV Set, Book Page Turner, Bed Position, Lights, Etc.

Hand Physiotherapy Device

Electromechanical Simulator Modules

Horizontal Shower Used for Bedridden Patients

Portable Laminar Airflow Surgical Clean Room

Heat Pipe Applications Used for Treating Hemorrhoids, Malignant Tumors, and Cervicitis

Voice-Controlled Wheelchair with Artificial Arm and Hand

Paper Money Identifier for the Blind

Toxicological Effects of Polyvinyl Chloride (PVC) Plasticizers

Cardiac Care Systems for Emergency Rescue Vehicles

Table 7 - Selected NASA Technology Transfer Benefits [29]

EDUCATION

Curriculum Supplements in Mathematics, Physics, Chemistry, Space Science, Physical Science and Biology

Soldering School for Electronic Components

Planetary Celestial Globe - Illustrates Interplanetary Motion

Hybrid Computer Used by Medical Students

Phonocardiogram Simulator Module Used by Nursing Students

Component Degradation Analysis Techniques Course

Methods for Using Optical Instruments

Computer Program Translating Guide

Optical Alignment Training Manual

Sanitary Techniques in Food Processing

Hazardous Materials Safety Handbook

Reading Instrument for the Blind

Table 7 - Selected NASA Technology Transfer Benefits [29]

ENVIRONMENTAL QUALITY

Carbon Monoxide Monitor - Commercialized as Air Pollution Monitor

Hazardous Gas Analyzer - Adapted for Use on Automobiles

Coal Desulfurization Process - Adapted from Lunar Module Rocket Engine Test Facility

Contamination Prevention Handbook - Used by Compressor Manufacturers for In-House Pollution Control

Remote Sensing of Air Pollutants Used Worldwide

Computerized Image Enhancement Used to Measure Quality of Water in Inland Lakes and Streams

Fan Noise Reduction Method - Used to Design Inexpensive Acoustic Panels

Apollo Program Quality Assurance Specifications - Offered by General Electric as Part of Consulting Services for Utilities Seeking Nuclear Power Plant Licenses

Pyrolytic Synthesis of Activated Carbon Used to Increase Raw Sewage Settling Rates by 100-fold in Orange City, California Pilot Plant

Satellite Photos Used for Making More Accurate Maps of Remote Areas such as Swamp Lands

Table 7 - Selected NASA Technology Transfer Benefits [29]

FOOD PRODUCTION AND PROCESSING

Weather Satellite Imagery - Used in Preparing Daily Fishery Advisory Charts for Commercial Fisherman in Eastern Pacific

Compressed/Freeze-Dried Food - Used as Compact Emergency Food Rations

Electronic Strain Gage - Used by Armour to Test for Hunters and Backpackers Hanging Beef Carcasses to Predict Meat Tenderness after Cooking - Used By Cattle Growers for Selective Breeding Programs

Fracture Toughness Tests - Used by Deere to Select Steel for Farm Tractors and Implements

Precipitation-hardened Steel Alloy for Apollo Command Module - Used in Fabricating Ram-jet Wind Machine for Frost Protection of Orchards

Clean Room Technology - Developed and Used by Pillsbury. Also used by FDA to Train Federal Food Inspectors

Contamination Control Handbook - Used by USDA Research Center in Louisiana to Train Employees

Microbiological Handbook - Used by Kraft Co. as Training Manual for Sanitary Techniques in Food Processing. Also Used by USDA to Develop Improved Milk Processing Procedures

Eutectic Salts for Low Temperature Batteries - Used to Develop Product that Shows Whether Frozen Foods Have Defrosted During Transportation or Storage

Table 7 - Selected NASA Technology Transfer Benefits [29]

Chapter 11

TECHNOLOGY ASSESSMENT

The problems of technology assessment are complex. To be comprehensive and useful, technology assessment must give careful attention to the interaction that occurs between government and industry. It must measure accurately the impact of technology utilization on social, political and economic patterns. It must establish priorities among the multitude of problems on the one hand and opportunities on the other that confront contemporary society. It must study methodologies of forecasting and planning as well as the structure of hierarchical aspects of independent assessments. It must evaluate alternative solutions to problems in the area that may compliment or conflict with proposed solutions to problems in another area. Technology assessment, in order to be a useful function, must be a quantitative rather than a qualitative measurement.

Joseph F. Coates, Office of Technology Assessment (OTA), defines Technology Assessment to be: a class of policy studies which systematically examines the effects on society which may occur when a technology is introduced, extended or modified, with special emphasis on those consequences which may be unintended, unexpected and delayed. In the past, though NASA's programs have been rich in the idea of technology transfer, technology assessment has been neglected. From the planning of their major programs, down to that of individual experiments, NASA does not consider technology assessment. Reference here is made to Chapter 5 of this paper, The Formal Project Review and Approval System.

I do not consider NASA's lack of consideration of technology assessment to be detrimental. I do not believe that the technology assessment should be considered by the agency which wishes to develop that technology. To do so might lead to a conflict of interest. Let me explain. Suppose NASA were required to perform a technology assessment on each major technology program in their R&D budget request. Suppose the technology assessment were required as part of the funding request submitted to OMB, reference figure 2 - NASA Budget Process, Chapter 2. If the resultant technology assessment proved favorable, there would be no problem to NASA including it in the package. However, what if the resultant assessment proved unfavorable? What would NASA do? Would they include the assessment? Would they remove the request for program funding from the budget? Would the resultant technology assessment be revised to make it more acceptable?

Research is neither good nor bad. The decision regarding the use to which research is put may be good or bad. I do not believe a research and development agency should be required to make such decisions. These decisions should be made by a governmental organization looking at a complete picture, not only a small portion of such a picture. Technology Assessment should be the province of such an organization. That organization could be CTA.

Chapter 12

POLITICAL INSTITUTION RELATIONSHIPS

Section 203 of the National Aeronautics and Space Act of 1958 authorizes NASA to enter into agreements with other agencies and cooperate with other public and private organizations. Section 205 authorizes NASA to cooperate with other nations, providing it is done within the framework of U.S. foreign policy.

Throughout its history, NASA has not only obeyed the letter of the law but has acted in the spirit in which the law was written. It has, through the years, conducted many cooperative programs with other agencies, state and local governments, regional organizations, private organizations, international organizations and governments. As NASA's budget declines, it is more and more taking the role as a service organization to various user groups. Consequently, NASA, in recent years, has significently increased the number of cooperative programs it conducts. Chapter 10, Technology Transfer, describes some of the cooperative programs which NASA is conducting with such organizations as: the Department of Agriculture, the National Oceanographic and Atmospheric Administration, U. S. Corps of Engineers, Mississippi, Georgia, Environmental Protection Agency, U. S. Coast Guard and the U. S. Geological Survey.

A major effort of the Office of Applications in FY-77 will be to increase interactions with the using community to even a greater extent than previously.[30] Interactions are designed to improve the understanding and awareness of the total user community of the NASA applications program and provide feedback which will guide the program. NASA is instituting, along with other federal, state and private organizations, User Working Groups in the areas of agriculture, water resources, land inventory and mineral and petroleum exploration. The members of these groups will be selected to be well qualified to define technical and operational requirements and economic considerations relevant to the technology development and transfer process in their areas.

The NASA User Visits Program, directed primarily toward states, focuses on the help NASA can provide to states with active remote sensing programs as well as states just beginning such programs. The program will also move toward increasing contact with regional organizations such as the Appalachian Regional Commission, the Southern Growth Policies Board, the Pacific Northwest Regional Commission and the Federation of Rocky Mountain States.

As part of the Landsat Program, NASA is completing a User Guide on the use of Landsat data in dealing with strip mining problems. This guide has four sections, directed toward four different audiences: legislators and governor's staffs, state agencies with statutory authority, coal companies and organizations concerned with environmental monitoring. Similar user guides are planned to address the applicability of Landsat to other disciplines, suggest sources of technical assistance for users, indicate information systems pertinent to earth resources and identify key activities and personnel in each of the states.

In the international area, there are many examples of NASA scientific cooperation. Experiencing worldwide publicity in 1975 was the joint US/USSR, Apollo-Suyuz mission. Although the major purpose of this mission was the development and test of an Earth orbit rescue capability for future manned space missions, many other experiments for receiving less publicity were carried out.

The European Space Agency (ESA) is designing and building Spacelab as a joint program with NASA. It is planned to launch Spacelab into Earth orbit aboard the Space Shuttle. In Spacelab, scientists and engineers of many countries will have the capability to carry out experiments requiring seven to thirty days of supervision in space. The project will cost the ESA member nations more than $400 million.[31]

Of six scientific satellites launched by NASA during 1974, five were built and paid for by other countries. NASA contributed the launching and some of the scientific instruments. The scientific findings are being shared. The five cooperative launches were: San Marco 4, with Italy, to measure the density of the upper atmosphere; Netherlands Astronomical Satellite, with the Netherlands, to investigate ultraviolet and Xray radiation from distant stars and galaxies; Ariel 5, with the United Kingdom, to detect and study celestial Xray sources; Intasat, with Spain, to measure the electron content of the ionosphere; Helios 1, with Germany, to probe to study the solar environment while traveling to within 30 million miles of the sun.[32]

Investigators from 50 countries and two international organizations have analyzed data from Landsat and the Earth Resources Experiment Package on Skylab, NASA's experimental manned space station.[33]

In 1976, NASA expects to have 19 launches, see Table 8. Only two of these are entirely NASA-funded missions. Another two are NASA cooperative missions with other countries. The remaining 15 will be entirely funded by commercial organizations, other Federal agencies or other countries. In 1977, NASA expects a total of 18 to 23 launches. Of these, only six will be missions primarily funded by NASA. Twelve to seventeen launches will be funded by non-NASA users. The NASA-funded missions will involve significant scientific and financial participation by European countries.[35]

January 1976

1976 PLANNED VEHICLE SCHEDULE

	Planned Launch Date	Mission	Launch Vehicle	Launch Site	Description of Mission
1.	Jan 15, 1976 (Launched)	Helios-B	Titan III Centaur	ETR	Second West German/NASA cooperative satellite to investigate the properties of and processes in interplanetary space close to the Sun.
2.	Jan 17, 1976 (Launched)	CTS	Delta	ETR	Canadian-US cooperative experimental communications satellite to develop and test the technology of high power satellite communications systems.
3.	Jan 29, 1976	Intelsat IVA-B	Atlas Centaur	ETR	Second of a series of improved Intelsat Consortium satellites. Reimbursable.
4.	Feb 19, 1976	Marisat-A	Delta	ETR	Comsat Corp. satellite to provide maritime communications services. Reimbursable.
5.	Mar 24, 1976	RCA-B	Delta	ETR	Second domestic communications satellite for RCA. Reimbursable.
6.	Apr 1976	NATO-IIIA	Delta	ETR	Communications satellite in synchronous orbit to perform communications relay for NATO. Reimbursable.
7.	Apr 1976	LAGEOS	Delta	WTR	Demonstrate relevant space techniques that will contribute to the development and validation of predictive models for earthquake hazard alleviation, ocean surface conditions and ocean circulation.
8.	May 1976	Comstar-A	Atlas Centaur	ETR	Domestic communications satellite for Comsat Corp. Reimbursable.

Table 8

	Planned Launch Date	Mission	Launch Vehicle	Launch Site	Description of Mission
9.	May 1976	Relativity (Gravity Probe)	Scout	WTR	Scientific satellite to make a test of Einstein's Theory of Relativity.
10.	May 1976	Air Force	Scout	WTR	USAF Scientific Payload. Reimbursable.
11.	May 1976	Marisat-B	Delta	ETR	Second Comsat Corp. satellite to provide maritime satellite communications services. Reimbursable.
12.	Jun 1976	Navy Transit	Scout	WTR	Navy navigation satellite. Reimbursable.
13.	Jul 1976	Indonesia-A (Palapa)	Delta	ETR	Indonesian communications satellite. Reimbursable.
14.	Aug 1976	NATO IIIB	Delta	ETR	Communications satellite in synchronous orbit to perform communications relay for NATO. Reimbursable.
15.	Aug 1976	Comstar-B	Atlas Centaur	ETR	Second domestic communications satellite for Comsat Corp. Reimbursable.
16.	Sep 1976	ITOS-E2	Delta	WTR	Operational meteorological satellite of the National Weather Service to provide daytime and nighttime cloud cover imagery. Reimbursable.
17.	Oct 1976	RCA-C	Delta	ETR	Third domestic communications satellite for RCA. Reimbursable
18.	Dec 1976	Marisat-C	Delta	ETR	Third Comsat Corp. satellite to provide maritime satellite communications services. Reimbursable.
19.	Dec 1976	Intelsat IVA-C	Atlas Centaur	ETR	Third of a series of improved Intelsat Consortium satellites. Reimbursable.

Table 8 (Cont'd)

Chapter 13

MANPOWER MANAGEMENT[36]

As previously discussed in Chapter 3, the NASA budget is declining. Consequently, manpower is also declining. Reductions in force have been necessary during the past few years throughout the NASA organization. NASA is not in the position of having to actively recruit personnel. Not only for the reason sighted above, but due to the fact that even during this period of a decreasing space budget, the space program returns enough interest for technical personnel such that NASA receives many more employment applications than the agency can accommodate.

Being a decentralized agency, staffing is performed at the field center level with only policy guidance provided by Headquarters. This guidance consists of the number of new or replacement spaces authorized, as well as the GS grade level for each.

Based upon the quality of research and development that has emanated from NASA over the years, it is interesting to note that no special or peculiar techniques or criteria are used in selection of professional personnel, other than the standard Civil Service requirements for grade level assignment. Normally, application forms and resumes are reviewed by potential supervisors and personal interviews are conducted.

Though the organization is decreasing in the number of personnel it employs, efforts are made to keep it from stagnating through the profusion of promising young scientists and engineers. Cooperative programs are run with several universities, whereby scientific and engineering students spend six months working at NASA installations and six months pursuing formal study at the university. Full time employment with NASA is available following graduation for those deemed qualified. Summer jobs are also provided for students pursuing technical educations, again with the opportunity of full time employment with NASA following graduation.

There is one exception to the lack of recruitment of professional personnel by NASA. This is in the areas of minority groups and women. Here NASA has made an intensive effort to interest qualified candidates into seeking positions in the space program. In the main, they have sought candidates at universities containing schools of science and engineering and having large minority enrollments.

NASA spends approximately 35% of its annual training budget on scientific and engineering personnel. These funds are spent on a number of different programs in an effort to prevent technical obsolescence and encourage personnel to work toward advanced degrees. NASA, either within the agency or in conjunction with universities or industry, conducts specialized training courses at the various field centers. Off-campus courses for university credit are conducted at the centers under the auspices of local universities. NASA has a tuition reimbursement program for its personnel, for these as well as any on-campus courses taken. Training funds are under the control of the various field center training offices and are generally allocated on a first come first served basis. This has been the case since sufficient training funds have been available to fill requirements. Should funding limitations develop, a procedure has been developed whereby the Training Officer, in cooperation with the Personnel Director at the various centers, would allocate the funds on a priority basis.

NASA has had a full time study program as well as the part-time programs discussed above. The agency has a policy of encouraging sabbatical leave for teaching, studying and research purposes. However, due to the restrictions on manpower and funding in recent years, the number of sabbatical has been severly limited and candidates are closely screened. NASA also sponsors approximately 25 to 30 people per year for fellowships such as Sloan, MIT, Woodrow Wilson, etc. These fellowships are awarded on a competitive basis. Candidates are nominated by their supervisors to a screening board at the various centers. The boards make recommendations to the Center Director. The director endorses certain of the candidates and their applications are submitted to a central panel at NASA Headquarters for final screening and selection.

Based upon NASA having a decentralized organization, another interesting training policy exists within the agency. Personnel are nominated by each of the field Centers on a competitive basis and selected for a one year program at Headquarters. The personnel work in management positions at Headquarters for the year in a combination of on-the-job training along with formal academic training including special courses and seminars. The personnel are then returned to the Center from which they came. The plan is to develop in these people an awareness of the requirements of management at the various levels and to increase the diversity of experience of personnel with high promotion potential at the field installations.

NASA may award three medals each year for exemplary achievement.

> The NASA Exceptional Scientific Achievement Medal is awarded for unusually significant scientific accomplishments which contribute to the programs of NASA, DOD or other government agencies. This award may be given to an individual whose creative efforts are high ordered and who has made important contributions to science and related technology either as a scientist or as an administrator. It is not required that the recipient be a NASA or other Federal employee.
>
> The NASA Distinguished Service Medal is awarded to any person in Federal service who by distinguished service, ability, or courage has personally made a contribution representing substantial progress to aeronautical or space exploration in the interest of the United States. The contribution must be so extraordinary that other forms of recognition by NASA would be inadequate.

> The NASA Exceptional Service Medal, the highest honor that NASA confers, is granted for significant achievement or service characterized by unusual initiative or creative ability that clearly demonstrates substantial improvement of engineering, aeronautics, space flight, or space related endeavors or administration and support of those endeavors which contributed to the programs of NASA. It is not required that the recipient be a NASA or other Federal employee.

In general,personnel administration at NASA tends to be extremely flexible. Rules do not exist governing everything an employee might do during a working day. Employees are expected to use good sense and make judgments on their own. The work environment is conducive to the conduct of R&D. The people operate in an extremely independent manner at all levels with what appears to be a high degree of job satisfaction.

EPILOGUE

This paper has presented what appears to be a highly innovative, well organized, federal research and development agency, NASA. The organization of the agency is decentralized which is conducive to effective R&D management. There is a budget split of 20% for research and 80% for development which, in my opinion, provides a higher-than-average research fraction compared to other federal agency R&D budgets. NASA was one of the first to implement the matrix form of program management within its organization. This management structure is today considered to be extremely effective in the management of large-scale development programs and has come into common use both within government and industry. Regarding the experiment organization of its space research vehicles, NASA makes considerable effort to achieve the maximum return for its research dollar. The agency has an extremely liberal patent policy intended to encourage university and industry participation in NASA programs in an innovative fashion. The unique university grant issuance program used by NASA is a model for other federal research and development agencies to follow.

Major efforts at NASA to assure development and utilization of the research conducted are the technology transfer programs, as conducted by the Technology Utilization Office and the Office of Applications. One has only to glance at Table 7 in Chapter 10 to discover the enormity of scientific advances brought into use through NASA technology transfer efforts. Many cooperative programs are conducted with other federal agencies, state and local governments, regional organizations, private organizations, international organizations and governments in efforts to both further space related research and development, and transfer the results to society.

Manpower management philosophy at NASA in the areas of personnel development, education, training, work rules, achievement recognition, financial return, and work atmosphere are geared to promote productivity and high job satisfaction for scientific, professional and nonprofessional personnel alike.

There are a number of negative aspects to the management of science at NASA which are not apparent upon reading this paper, nor can they be substantiated, but are the opinions of the author based upon discussion during the interviews conducted. Space research and exploration no longer is one of the major national objectives that it was in the 1960s. The NASA budget has decreased dramatically in the past ten years. In my opinion, the prime objective of the NASA administration has become maintenance of its annual budget at a constant level. The number of high risk, innovative projects undertaken by the agency has fallen significantly from what it was during NASA's glory years. In order to maintain a constant budget, it is my opinion that the administration maintains it cannot permit projects to fail. This position stifles innovation. Organization at both the Headquarters and Center levels has become more complex. More red tape is involved in acceptance of a proposed project. Reviews are more critical. More attention is paid to "procedures" than to "substance." Organization is in a state of flux. Again, this stifles innovation. As an example, the organization at Goddard Space Flight Center has been substantially revised four times in the past three years. The NASA budget increased in an exponential fashion during the 1960s, with the present entrenchment, low risk policy of the administration, NASA is exhibiting the symptoms of stagnation. Unless these stagnation symptoms are treated and present policy is reversed, in my opinion, the NASA budget will not remain constant; it will decrease and the innovation that has characterized NASA since its inception in 1958 will diminish to the point of being nonexistent. Should this occur, NASA will then become a service agency providing such capabilities as launch and tracking facilities for other organizations.

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[29] NASA Pocket Statistics (Washington: NASA, September, 1975), pp. 37-43.

[30] Mathews, Charles W., op. cit.

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[32] Ibid.

[33] Ibid.

[34] Fletcher, James C., op. cit.

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[36] All information contained in this chapter was obtained through personal interviews. Specific references to each interview will not be made as explained in the Interview section at the end of this paper.

INTERVIEWS

Interviews for the purpose of obtaining factual information and opinions of the interviewees pertinent to the preparation of this paper, were conducted during February, March and April, 1976. No specific references are made to any interview, within the body of this paper, in respect to the privacy of those individuals willing to answer my questions.

Name	Organization	Facility
Sidney Alterescu	Technology Utilization Office	Goddard Space Flight Center
Alice J. Beck	Technical Asst., Office of Financial Management, Office of the Comptroller	Headquarters
Stanley Corwin	Chief, Contract Management Branch, Procurement Division	Goddard Space Flight Center
Susan K. Keener	Program Management Division, Office of Personnel Programs	Headquarters
Louis A. Koschmeder	Projects Directorate	Goddard Space Flight Center
Neil F. Lamb	Office of Procurement	Headquarters
Albert P. Little	Asst. to Comptroller	Headquarters
Jerome D. Morris	Chief, Management Branch, Office of University Affairs	Headquarters
Denia S. Nappier	Chief, Information Center, Office of Institutional Management	Headquarters
Jurgen G. Pohly	Chief, Minority Research, Office of University Affairs	Headquarters
Kathryn C. Walker	Director, Program Management Division, Office of Personnel Programs	Headquarters

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THE MANAGEMENT OF SCIENCE AT THE U.S. DEPARTMENT OF AGRICULTURE

by

Bobby L. Mitchell

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INTRODUCTION

The Department of Agriculture (USDA) is directed by law to acquire and diffuse useful information on agriculture subjects in the most general and comprehensive sense. To accomplish this purpose, the Department functions in the areas of research, education, conservation, marketing, regulatory work, agricultural adjustments, surplus disposal, and rural development.

The act of Congress, approved May 15, 1862, created the Department of Agriculture, which was administered by a Commissioner of Agriculture until 1889. By the act of February 9, 1889, the powers and duties of the Department were enlarged. The Department was made the eighth executive department in the Federal Government, and the Commissioner became the Secretary of Agriculture. The organizational structure of the Department is shown in Appendix A.

This paper will deal primarily with agricultural scientific research and its development, eventhough there are various agencies within the USDA that are involved in different types of research.

The USDA is authorized by Congress to conduct both basic and applied research (agricultural). There are several basic authorizations, which are general in nature and form the framework wherein the Department conducts and supports research. In addition, there are 28, or more, specific authorizations which cover specific studies of farm crops, animals, markets, the construction of specific laboratoratories, and other agricultural topics and problems.[1]

The general authorizations, on which the Department's continuing research programs are based are contained in nine Acts of Congress.[2] These acts are in Appendix B.

Agricultural research activities are administered by six agencies within the Department and the National Agricultural Library. The six agencies conduct and/or support a comprehensive agricultural research program in crop and livestock production, in plant and animal diseases, in farm management, in forestry, in entomology, in soil and water conservation and management, in market quality and transportation facilities, in nutrition and consumer use of food and fiber, in agricultural engineering, in farm cooperative organizations, in processing and utilization of agricultural products, and in agricultural economics. Both basic and applied research are undertaken as dictated by the problems of national and regional concern to agriculture, as well as those problems that involve international relationships. The six USDA research agencies and the scope of their activities are briefly described as follows:

A. The Agricultural Research Service

This is the central research agency in the USDA. It will be described in detail in subsequent sections.

B. The Forest Service

The Forest Service conducts research in the entire field of forestry and the management of forest and related ranges. It also conducts research to develop new and improved products of wood, to increase efficiency of utilizing forest products, and to advance the efficiency and mechanization of forestry operations.

The Forest Products Laboratory at Madison, Wisconsin, is the national center for research on wood products. The program covers all aspects of wood from its formation during growth of the tree to its chemical makeup and physical form as chips, as pulp, or as chemical constituents is the subject of intensive studies.

C. The Farmer Cooperative Service

The Farmer Cooperative Service helps farmers and other rural people develop new cooperative services and advises rural co-op officials to improve or expand existing cooperatives. The research program is focused on uniquely cooperative aspects of organization structure, financing methods, cost and efficiency, merchandising methods, management practices, and member relations.

D. The Cooperative State Research Service

This agency administers formula and special grant programs in support of programs in State institutions. The Cooperative State Research Service provides to the research administrators assistance in coordinating research among the State institutions and between them and the USDA. This assistance includes participation in long-range program development at each institution, in regions, and nationwide.

E. The Statistical Reporting Service

The Statistical Reporting Service provides the statistical intelligence about economy of the country. This entails nationwide crops and livestock estimates and special surveys of market potentials for agricultural products.

F. The Economic Research Service

The Economic Research Service's program is designed to provide economic intelligence for the Department and other Federal decision makers, farmers and related industries, and the general public. The findings of this research effort are made available to the users through research reports and through economic outlook and situation reports on major commodities, the national economy, and the international economy. The studies are directed toward finding answers to current and emerging problems of agricultural production, marketing, and resource development.

The ERS has recently conducted environmental impact studies to relate the economic impact of actions taken or pending before the EPA. Such studies included the economic effects of restricting the use of DDT on cotton, of restricting the use of 2,4,5,-T in rice production, of discontinuing farm use of Aldrin and Dieldrin, and of pollution abatement in family livestock production. In my interviews with the ARS it was revealed that the ARS does a significant amount of technological assessment on both new and old technology. From my understanding it does just as much TA on ARS's technology as ARS does.

Some of these research agencies will be dealt with later in various ways each plays a supporting role in the research of ARS.

There are those who believe that the USDA has had its day despite its excellent background in research and promotion.

There are those who believe that the USDA has become too comfortable and complacent. President Nixon's reorganizational proposal of 1971 would have carved the present USDA into four parts, each to be fitted into one of the four proposed new domestic departments.[3]

The old USDA developed as an educational, scientific, and statistical agency, and by 1910 it had gained a distinguished reputation in these fields of activity.[4]

The USDA of the 1930s derived from a new political agenda, much of which was later to be stricken due to pressures upon the Department, although the Department did achieve a record of competent service in these areas. Prominent among the features of many programs (USDA) during the 1930s was the provision for client participation in the structuring and implementation of local programs.

Later this client involvement was criticized as a mechanism which made the agencies beholden to private interests. Political scientist Theodore Lowi felt that these client linkages were an Achilles heel of New Deal-type pluralism.[5]

Similarly, Robert Eyestone utilized a life-cycle concept to describe the USDA's recent history, in which he maintained that a bureaucracy proceeds through three stages, beginning with a commitment to help the whole sector or class of people and backed by wide public support, but proceeding into a period of political entrepreneurship, in which the agency must generate its own political support from the particular clients it chooses to serve. Finally the agency passes into a "self regulatory" status in which its clients have gained control over it.[6]

THE AGRICULTURE RESEARCH SERVICE

The Agricultural Research Service was established by the Secretary of Agriculture on November 23, 1953, under the authority of the Reorganization Act of 1949 (5 U.S.C. 133z-15), Reorganization Plan No. 2 of 1953, and other authorities. It is the principal research agency of the USDA. Its research assists agriculture and affects the well being of all Americans.

The agency conducts a diversified national research effort to provide farmers with better ways to grow and market their products, and consumers with an abundant and varied supply of food and fiber. On the international front, the agency provides foreign countries with both agricultural knowledge and improved agricultural products.

Nearly 9,900 people are employed by the ARS on a full-time basis. Approximately 2,700 of these employees are scientists and engineers. Most of the employees are located at field research stations, experimental farms, and laboratories throughout the United States.

The Administrator of the ARS is responsible for maintaining a national program for agricultural research that will meet the needs of American farmers and consumers. The ARS serves the research needs of the action and regulatory agencies of the Department of Agriculture.

The ARS program is directed to providing new knowledge and technology in six major areas of research. Each of these includes basic and applied research directed toward developing new technologies needed to keep U. S. agriculture efficient and competitive both at home and in world trade.

The six areas of research are directed toward: Increasing farm production efficiency; reducing the cost of marketing agricultural products and developing new and improved existing products and processes; improving the environment and developing effective use of natural resources; reducing food related health hazards and improving family living; providing new knowledge of human requirements for nutrients to maintain good health as well as sources of these in food; and developing foreign agriculture and markets.

The first two named areas of research, farm production efficiency and marketing agricultural products, will be the main types of research dealt with in this paper.

The research objectives in the farm production efficiency area include: The discovery, development, testing, and production of crops and livestock with improved genetic, physiological, and nutritional yield characteristics; the protection of animals and plants from environmental stress factors ; and the development of improved and effective insect, weed, and disease controls, including safe pesticidal and alternative methods of pest control.

The research objectives in the area of marketing agricultural products include: The conducting of studies on the performance of marketing systems for agricultural products, development of food products having high protein content, as well as new and improved animal feeds, textile products and industrial products from crops and livestock.

The ARS is organized into four regions: Northeastern, North Central, Southern, and Western. Regional Deputy Administrators are responsible for providing program and administrative management of ARS programs within their assigned regions.

Within each region, location leaders serve as a focal point and as the principal ARS contact with State agricultural experiment station directors, department heads, and industry groups on general location matters. Research leaders provide line technical supervision in an assigned research area at a location. For a more complete depiction of research sites, see Appendix C.

The ARS also conducts foreign-based research mutually beneficial to the United States and the host country which can be advantageously performed in foreign research institutions and universities. This program is carried out under the authority of Public Law 480, as amended, by the utilization of foreign currencies generated from the sale of surplus agricultural commodities.

The Research and Policy Committee of the Committee for Economic Development states that the nation's public institutions for agricultural research are among the oldest and most distinguished in the world and have recently showed signs of age and a lack of imagination in approaching questions that are critical to future food supplies.[7] The report goes on to state that Congressional pressures have sometimes prevented needed changes, thus slowing the redirection of research effort. Administrators of agriculture research establishments have often become identified with maintenance of the status quo at the expense of innovation. Efforts to reorder research priorities in the past ten years have sometimes failed because established institutions and projects could not be adapted to future needs. Persistent self-examination has not yet renewed the vigor of agricultural research in the United States.[8]

FEDERAL-STATE AND INSTITUTION RELATIONSHIPS

The Hatch Act of 1887 provided for the establishment, in each State or territory, of a department of the land-grant institution to be known as State agriculture experiment station.[9]

The McIntire-Stennis Act of 1962 authorized support for a cooperative forestry research program at State agricultural experiment stations and forestry schools. It brought 19 additional institutions into the same harmonious working relationships with USDA as the 1862 land-grant universities under the Hatch Act. The Facilities Act of 1963 and competitive project grant programs under the Special Research Grants Act, PL 89-106 have helped to build further excellence into the academic-science framework. The Colleges of 1890 and the Tuskegee Institute receive Federal funds through USDA and PL 89-106.

There are 55 State agriculture experiment stations. Two States have two each. There is one in each of the other 48 States, Puerto Rico, Guam, and the Virgin Islands. The experiment station director is responsible for direction of the research program at each State station. A very important aspect of the State program is that there is local direction of the program by the station director within the college of agriculture and the land grant college.

The typical agricultural experiment station is one of three branches of a college of agriculture in the State land-grant university. It involves a wide array of biological, physical, and social science disciplines. The experiment station, the primary agricultural research organization of the State, is supported by funds from several sources--State taxes, Federal funds through the USDA and granting agencies, and grants from private industry and foundations.

The research function of the typical experiment station is closely intermeshed with resident instruction and extension; in fact, the same scientist is often involved in at least two of these functions.

Resident instruction involves undergraduate and graduate students. Over the years, graduate instruction has achieved an increasingly prominent role of the typical college of agriculture, school of forestry, or college of 1890. This graduate instruction is in close collaboration with the associated experiment station research system which produces most of the nation's agricultural scientists.

In addition to intracollege coordination among the research, teaching, and extension functions, the State experiment programs often involve USDA input. USDA researchers are located in many university departments and work cooperatively with those departments. These scientists often carry joint titles with the USDA and the university, and many have graduate students or teach seminars or advanced graduate courses.[9]

From a functional viewpoint, the lines which separate the various roles are subordinated to the ultimate goal of solving problems and training future scientists and agriculture leaders.

The relationship between land-grant universities, State experiment stations, and USDA represents a unique and potent force for compiling scientific knowledge and getting it into the hands of people for intelligent action in their own behalf. On an ever-increasing scale this knowledge and skill has been brought to bear on the solution of troublesome agriculture problems impeding the growth of the undeveloped nations.

The extensive facilities and highly qualified staffs in the State experiment stations are largely due to continuing and dependable funding support. The nature of the system permits the bringing together of Federal, State, and private support for research and graduate education. The intent of

Congress in providing additional support for agricultural research on a formula basis with matching requirements has been amply met. State and other non-Federal support of experiment station research has been several times the Federal contribution and continues to grow.[10]

With this USDA-SAES institutional arrangement there have been problems as one might expect.

The Committee on Research Advisory to the USDA made the following statements in its report:

1. Acknowledgement must be made of findings that indicate that much of agricultural research is outmoded, pedestrian, and inefficient, and that bold moves are called for in reshaping administrative philosophies and organizations, in establishing goals and missions, in training and management of research scientists and in allocation of resources.
2. The Committee found evidence that, in the allocation of resources for agricultural research, grossly inadequate support was given to basic sciences that underpin agriculture; that the agriculture establishment seems to have an excessive number of field offices and laboratories with an undesirably low level of coordination of State agricultural experiment station-USDA efforts; that disproportionate commitment of funds to some areas has resulted in under-

commitment in others and thereby to weakening the vitality and balance in the whole program.

3. Evidence was also found that in the research itself there is an unwarranted duplication of effort in some areas and thus a wastage of resources; that far too much of the research is of low scientific quality, indicating low ability of some researchers, or poor administrative management of the researcher.

PROJECT SELECTION

Research and development organizations with their goals of understanding nature, inventing new technologies, and innovating from existing technologies are enterprises in which oriented thinking is a fundamental necessity. In anticipating and responding to their changing environments and the evolving needs of their clientele, these organizations must give simultaneous consideration to such questions as what is or will be needed and what is or may become technologically feasible. These are not easy questions to answer. For in many cases a basic premise of project selection is that there are more research proposals generated than there are implementing resources. Research spending in the USDA has dropped from 28 percent in 1924 to 3 percent in 1975.[11] In order to maximize benefits from the R&D function, a process called project selection is employed by or for management to decide which projects should be included in (or excluded from) the R&D program. The project selection process may be highly subjective, intuitive and informal, or it may be based on large amounts of data fed into computerized selection models in a formal procedure, or it may be any combination of these two extremes.

Of course, selection of projects is but one of a series of interrelated steps in the total research management process. One step in the process should not stand alone, plucked from the total context of the research management process:[12]

Idea Generation
Relationship to Corporate Objectives
Project Selection
Project Management and Control
Communications with Other Functions
Translation to Commercial Reality
Post Evaluation

Project selection at the USDA takes on the following procedure:[13]

1. National goals are set by OMB.
2. Authority of USDA to contribute to these goals.
3. The ARS goes to research line managers to determine their capability.
4. Line managers identify proposal funds, benefits etc.

This is a well formalized procedure in which the ARS management and planning system plays a great part.

USDA also supports State agricultural experimental stations through the Cooperative State Research Service. These experimental stations do much detailed work in adapting results of USDA applied research to local areas. This frequently involves derivative inventing or developing which closely associates with innovating. Within USDA inventive programs, inputs are processed straight forwardly. Project selection occurs after each processing stage but can vary with outside factors. For example, crop yields may be increased by reducing insects, irrigating, or using fertilizers. Selection of the most useful approach may change because of side effects or of relative factor input costs. Outside factors can have considerable influence because of pressure group activity.[14]

Example: In the twenty year development of screw worm fly control technologies, many approaches were considered before, and along with,mass sterilization. Direct wound treatment methods were perfected and publized as stop gaps. Once the biological approach was adopted, the supporting technologies for raising the flies on whale meat, mass sterilization using cobalt 60, distribution over large areas, and measurement of their effectiveness had to be developed step by step, trade-off by trade-off.[15]

The United States Department of Agriculture controls new technology generation through priorities and allocation of resources, but because of this activity is mostly internal and centralized, the control is simplified. To the extent that USDA works with all states, the work must be carefully coordinated. Suitability evaluations during the past twenty years have caused a gradual shift in priorities from increasing production to improving quality for consumers.

For several years, the USDA Research Program Development and Evaluation Staff functioned in both control and systems review. The staff coordinated the Department's inventive activities and audited internal management. In addition to this internal review, Congressional committees on agriculture made substantial inputs into redirecting USDA inventive efforts.

The selection process for new project ideas in the USDA and in other Federal agencies has been different from that in the private sector. However, I do think that the private or industrial has something to offer to the Federal sector.

William M. Whaley and Robert A. Williams[17] offer the following ten-step system for project selection:

1. Develop a checklist of criteria defining the bounds within which the R&D organization will function.

2. As project opportunities are presented for consideration, determine whether they meet the qualitative criteria of acceptability.
3. Estimate the value in dollars of the projects which pass the first decision point. The value estimate is independent of risk or cost of the project and deals only with objectives.
4. Establish a minimum value level which is commensurate with the size of the corporation. Measure each project's value against the established minimum and reject those which fall below it.
5. Assign the surviving R&D projects and objectives to appropriate segments of the R&D department for establishment of technical approaches. This should be given major emphasis through the line organization and should employ all available resources to assure that the best approach or approaches are proposed for each project.
6. Establish an estimated R&D cost to carry out the technical approach.
7. Compare projected costs with established maximum-tolerable costs for R&D projects. Projects which are too costly in comparison with the total R&D budget should not be undertaken. However, allow for management override at this point.

8. Examine the surviving projects for the cost of commercial application of each objective in the context of the technical approach chosen.
9. Develop standard financial analyses for the remaining projects using the best data obtainable. There would normally be included: Return on investment, cash flow, payback time, and production cost.
10. Make final decision concerning each project:
    a. Approve.
    b. Reject (but retain data for future use as technology/market situation changes).
    c. Send back for rework to determine whether a better technical approach is possible.

There are many more project selection criteria and procedures used in the private sector that will eventually have or should have direct application in the public sector or Federal government. As previously stated, USDA research funds have been on the decrease for the last quarter of this century when compared to its overall expenditure of funds. In the future. Congress through its Office of Technological Assessment and the New Congressional Budget Office will be looking more scrutinously at how research funds are spent and their justification.

TECHNOLOGICAL ASSESSMENT

Research activities of the USDA are generating technologies and then diffusing them by informing, innovating, and integrating. Technological assessment at the USDA has not been as effective as one would like it to be. I call to attention the problems we are now encountering with pesticides, herbicides, DES, and the problems that foreign governments are currently experiencing with the "green revolution."

Daniel Roman states that the objective of technological assessment is the systematic examination of anticipated technological consequences.[18] In defining technological assessment David Kiefler says: Technological assessment is an attempt still halting and uncertain--to establish an early warning system to control, direct, and, if necessary, restrain technological development so as to maximize the public good while minimizing the public risks. It is, no less, a new approach to allocating scientific resources, setting technological priorities, and seeking more benign alternatives to technology already at hand.

Hugh V. O'Neill[19] defines technological assessment as the analysis of the inputs of new technology and innovative uses of older technology. Where this analysis is wide in scope, including economic, political, legal, biological, social, and environmental impacts, it tries to anticipate both opportunities and negative results. This includes both indirect spillover and long term effects, as well as the more direct results.

As one already is aware, technology is critical for sociological welfare, economic growth, and political survival. Unfortunately, technology has not always been an unmixed blessing. In solving political or economic problems by technological expansion, there have often been unforeseen and undersirable side effects as well as unfavorable publicity. Technological implications have to be explored and understood relative to potential benefits and problems. Technology must be planned. Technological forecasting and technological assessment are new tools designed to give better insight and, hopefully, provide guidance as to whether to undertake the development of a new technology. Technological forecasting attempts to determine with a high degree of confidence future technological developments. Technological assessment has been almost exclusively localized with the Federal government. Government commitment is practically dictated by the magnitude of the problem and the diverse groups generally involved.

At the U. S. Department of Agriculture assessment on the same technology is performed by two different agencies, the ARS and the ERS[20] (Economic Research Service). The Agriculture Research Service develops the technology and determines its feasibility in achieving intended goals. The Economic Research Service is concerned with the cost benefit aspects of this same particular technology. It also looks at some of the sociological aspects of the technology. Congress enters in occasionally on the political implications of a technology question. USDA agencies propose, and farm units dispose. If USDA proposes impractical technology, the farmers reject it. Administrators support successes and study failures to determine what went wrong. Feedback is not always obtained in a timely manner and corrective action then comes too late.

Some USDA programs for long term gain, like watershed improvement & conservation, do not weigh heavily immediate gains; but normally, new technology either pays off in the short run or it does not.[21] If it pays off, however, there may be undesirable side effects or excessive support requirements. Screw worm fly control had no discernible undesirable effects on the farmer. Its success resulted from carefully preparing the project to fit the needs of farmers, obtaining their approval and cooperation, and using constant and near real-time feedback on the progress of the project. The main feedback for the total program was the realization that reinfestation from Mexico prevented a final solution and that the project would have to be continued as a permanent USDA activity.

The use of agricultural pesticides and herbicides are now revealing their long term implications. Large increases in the use of pesticides are necessary to increase food production. All types of insecticides, fungicides, herbicides, nematocides, and rodenticides are needed. If man tries to impose total control over pests by chemical means, he poisons his own environment and that of the myriad of natural life forms on which in many subtle ways the life of man depends. If man fails to control the parasitic pests that multiply by consuming his growing food, man faces mass starvation. Wise management of resources requires the achievement of a balance between these two opposite hazards. Only by increasing his understanding of the relationships within nature,and the effects of pesticides on the consequential forms of life and their interrelationships, can man progress toward this balance. These sentences exemplify what technological assessment and transfer are all about. The long term implications of agricultural pesticides upon the environment were not assessed for the long term effects. A question that should be considered is, was it feasible to determine long term impacts and effects at the initial stages of this technology? Pesticides enabled more crops to be harvested and were cost effective for short range planning. The long term effects of Dieldrin and Aldrin and some other analogues of DDT have proved not to be so cost effective in the long range outlook. This is another example of how complex technological assessment is and why all aspects, tools, and methodologies should enter into assessment.

We are all aware of diethylstilbestrol (DES), a growth hormone known to cause cancer and birth defects in both animals and human beings. Unfortunately our technological assessment did not reveal the long term implications of this agricultural agent. Sweden refused to import United States beef that had been raised on feed containing DES. Twenty-one countries, in fact, banned DES in livestock before it was banned in the U. S. in 1973.

Eventhough technological assessment can be a continuing process, it should be performed before the technology is developed, transferred, and utilized. However, it is not always feasible or possible for this to take place.

The "green revolution" productivity requires high capital, increased fertilization, and close control of water supplies. All of these are imposing constraints. The Arab-Israeli War of 1973 resulted into an oil embargo that caused astronomical oil price increases. This resulted in an increase in price for energy and fertilizers. A situation resulted for the underdeveloped countries using this technology that made the "green revolution" not cost effective. This experience demonstrates again that the transfer of technology to develop production systems is complex and can have unexpected ramifications.

Technological Transfer

The technology developed for agriculture and its problems has been transferable to other problems and areas for which it was not originally intended. Agricultural scientists were the first to link an insect vector to the spread of any disease.[23] In tracing the cause of Texas Cattle Fever to the fever tick, they opened the way to control of such human diseases as malaria, yellow fever, and sleeping sickness.

They developed techniques for mass production of penicillin and, subsequently, other drugs. They discovered that Vitamin D could be supplied by direct radiation of ultraviolet light, which resulted in the elimination of rickets--not only in farm animals, but also in humans.

Agricultural scientists discovered streptomycin, the first of the wonder drugs to show hopeful results in the treatment of tuberculosis. Their research also led to the isolation and identification of dicumarol, a compound now widely used in man. Some estimate that the use of this drug saves the lives of one out of every three persons stricken with coronary thrombosis.

One method of diffusing technology in the USDA is its Current Research Information System (CRIS). It involves a research project system providing for the interchange of information among scientists. It includes information essential for research planning, coordination, and management. CRIS includes projects for all research conducted.

Technology should be approached as a holistic concept. Technology is not the exclusive province of any segment of our society. It must be planned. In order to plan technology, one must know what to expect from it. Technological forecasting should come into the scheme of things. There are various technologies related to technological assessment which have recently been developed, such as operations research, systems analysis, management science, cost-benefit and cost-effectiveness analysis, These latter two technologies are used by the ERS of USDA in its technological assessment program. To illustrate where technological assessment is integrated into the decision-making process, one might consider operations research studies feeding up to broader level systems analysis, and these in turn feeding up to policy analysis and decision making. The decision maker must make difficult choices using both qualitative and quantitative information and within the real world constraints of his position, but technological assessment should assist in reducing or at least identifying uncertainty, as well as suggesting techniques for gathering additional information. In a report prepared for the Committee on Domestic Technology Transfer by the National Science Foundation[24] it was found in this study that a very small number of agencies said that they used modern formal quantitative measures of change in their user group as one method of evaluating program effectiveness. The USDA was included in this small number.

As has been illustrated previously, it has become increasingly clear that unless more forethought is given to new applications of technology, these applications can have seriously detrimental effects impacting a widening sector of the public sector. Within the USDA, I have not found the direct participation of the public. I would suggest the participation of citizen action groups, citizen legal suits, regional plan associations, and on the Citizen Advisory Council of the Congressional Office of Technology Assessment.

RESEARCH GRANTS

The Cooperative State Research Service administers Federal-grant funds for agricultural and forestry research to the land-grant agricultural experimental stations, forestry schools, and other eligible institutions located in the various states and Puerto Rico.

Appropriations under the Hatch Act provide funds annually for 53 agricultural experiment stations. The funds appropriated under this act are disbursed according to a formula established by law, as follows:

1. Twenty percent alloted equally by state.
2. Not less than 52 percent allotted to the States based upon a) the relative rural population of all states, and b) the relative farm population of each state to the total farm population of all states.
3. .Not more than 25 percent allotted to the states for cooperative research in which two or more State stations are ~~sme~~ cooperating to solve problems of more than one state.
4. The remaining 3 percent to the Secretary of Agriculture for administration.

The CSRS is responsible for reviewing the projects for acceptance and determining whether the Federal-grant funds allotted to each station are used in accordance with the statutory authorization. Progress reports are submitted to the CSRS annually and are reviewed by the technical staff at headquarters. Since projects run for an average of five years, only about 1,500 to 2,000 new projects are submitted for approval each year.

A CSRS official[25] advised that,, until recently, there was a policy of the technical staff reviewing projects at station level each year for technical competence. A scientist from headquarters would review all projects at the station even though he had technical competence in only one discipline. Since he could not be an expert in all disciplines, it was difficult for him to be objective in programs with which he was not familiar. Now, under a new policy, each scientist visiting a station reviews only those grant projects he has the technical competence to evaluate. This results in visits less frequently such as once every three to five years instead of once a year.

A CSRS official advised an investigative staff that very little influence can be exerted by his office on the State's grant programs.[26] He pointed out that a previous Administrator had attempted to give direction to the State programs and was removed from office after the State officials complained about his interference in their programming. Recommendations have been made on previous occasions to make the position of the CSRS Administrator a political position with an appointment of someone who would more typically represent the State position.

The CSRS official advised that it is difficult to terminate research projects which do not appear to be successful,or to shift priorities. The State Agricultural Experiment Station officials view the projects as their projects and under their control. He stated that there are approximately 16,000 research projects at the experiment stations and 1,000 scientists are involved in these projects. Approximately 7,500 of these projects have Federal funds. He said that even if it was decided that a particular project should not be funded in future years with federal funds, the State might continue the effort on its own and shift the Federal funds to another project, if in the opinion of the State the project had value.

RESOURCE MANAGEMENT: INFORMATION

The need for information, whether required by scientist, technologist or technician, has several sources. There is first a need to be aware of what is currently going on in one's field

The traditional scientific communication system has evolved over the last few hundred years from a small number of stylized, normative patterns: the scientific meeting, the scientific journal, the scientific book, and the scientific library.

The first two media have traditionally been organized through the learned and professional societies.

In recent times many important changes in the organization of scientific institutions, and in the support and utilization factors of scientific endeavor, have caused analogous changes in scientific and technical communication patterns which have introduced many new media and have placed great pressures upon the older media. Thus, as science and technology have become economically significant elements, commercial interests have entered on the scene and are now involved in a host of enterprises which involve all phases of communication systems.

At the USDA (ARS) the system for communicating research information to and among scientists is substantially different from that of disseminating information to the small, part-time farmer and gardener . In general, it is common practice for the scientists to publish the results of their experiments in varied scientific journals that are published in our country and internationally. These journals cover many disciplines scientists need to keep up to date with current progress. This need for contemporaneity is part of the culture of present day science. To know the contemporary state of the art is essential if the research worker is to leave his mark on scientific and technical development. A researcher worker does not want to do what others have already done and he does not want to follow a path which has been shown to be erroneous. But as much as that he needs to feel himself in the main stream of the best of contemporary work. The quantity of research is so great and the quality so widely distributed that any research worker must know what others are doing so that his own work will benefit from their innovations.

Scientists and technologists thus feel a pressing need to keep up to date-----to know not only what has appeared in print, but also what has not yet appeared in print at the moment. It is not enough to know the finished scientific product; it is necessary to know what is in the state of production. Scientists do not want to know about the work of their contemporaries some years after it has been done. A really speedy flow of information is regarded as much more urgent in most areas of science and technology nowadays than was felt to be the case in earlier periods in the history of research in these subjects.

Professional journals publish the work of ARS scientists and are read and cited frequently by scientists who may be doing similar work. The ARS scientists on the average publish about 3,000 articles annually in various journals. In addition, scientists of the ARS often attend professional meetings where they present papers and discuss new research with other colleagues. Frequently, these papers are gathered and published as proceedings. See Appendix D.

The ARS also publishes annually more than 200 technical publications on research; these are made available on request to professional and technical people.

Another means by which scientists keep informed on new research is by use of the telephone to exchange information on new research since many of them in the specialized disciplines are on a first name basis; subscription to current awareness services such as "SSIE"; "CRIS"; and the various services provided by NTIS.

The Smithsonian Science Information Exchange (SSIE) provides an invaluable means of keeping the ARS research investigator and the research manager informed. A search of the SSIE data base can provide information on research in progress in a specific field in ARS, the ARS researcher can search the data base to find out about projects dealing with problems similar to those that he is investigating; project notices from SSIE can help identify principal investigators with experience in particular areas, as well as organizations currently funding research in specific fields. The research manager has been helped by finding out about ongoing researche and special expertise to help solve a problem (a particular research problem).

The Current Research Information System (CRIS), a system initiated in the USDA, is also an invaluable communication and information means to help the USDA scientist and researcher to keep abreast of research in an area of special interest.

Some of the functions of CRIS are; It tells the scientist or researcher what investigations are underway right now and can tell one about current progress in a particular investigation as reported by the respective investigators within the previous 1 to 12 months; it can tell you the names of these investigators whom you have missed, both those who are working in your specific line of study and those working in allied fields or areas; and this supplied information enables one to find out whom you should talk to at meetings, whom to visit on your way to and from the meetings, and whom you must write to for information.

CRIS searches are provided to all agencies of the USDA, to State Agriculture Experiment Stations, and State extension services and the other State cooperating institutions. Any employee of these organizations who needs CRIS information may request a search, there is no charge.

To provide you with information about what's currently going on in your research area, CRIS will search about 24,000 research work unit (project) descriptions from six U.S. Department of Agriculture agencies.

In resource management of information the USDA seems to be adequate, especially in the utilization of its Current Research Information System. In the Hearings, before the Subcommittee on Science, Research and Technology, it was pointed out that the USDA had an impressive system for dissemination of scientific information to those in need to know. Mr. Thornton stated at these Hearings, "I am tremendously impressed with the structure and quality of the research apparatus in place and its ability to disseminate scientific information practically to those people who need to have that information."

The National Agricultural Library (NAL) also plays a very important part in helping to disseminate information to the scientist or researcher in need of information. The products and services of the NAL are available to USDA personnel, the worldwide agricultural community, other Federal government agencies, land-grant universities, and others with an interest in the Library's resources.

The resources of the NAL consist of books, periodicals, manuscripts and materials in non-print forms on such diverse subjects as technical agriculture, farming, botany, chemistry, entomology, forestry, soil science, food and nutrition, water resources, rural society, and law economics pertaining to agriculture. Substantive publications of the USDA are included in the collection.

In addition to its usual collection activity the Library has facilities for housing and maintaining special gifts such as rare books, historical manuscripts, and special subject collections. A collection of rare and historically important volumes has been acquired over the years. Many of these rare books are in the field of botany and include fine specimens of lithographs, as well as a strong collection of the original works of Linnaeus.

Information materials may be obtained from the NAL by loans, interlibrary loans, by mail, by paid copy service and code-a-phone services.

RESEARCH MANAGEMENT

Agricultural research is managed through a complex system of Federal and State agencies, including the Agriculture Research Service, Cooperative State Research Service, Economic Research Service, Statistical Reporting Service, and some 68 land grant universities located in 50 different States.[27] The large numbers of administrative structures have been charged with reducing the quality of research completed by scientists. The "Pound Report" of the National Research Council (Report of the Committee on Research Advisory to the USDA, April 1972) found that administrative structures and philosophies reduce the decision-making power and freedom of movement of the scientists, with repressive effects on the vitality of science. This committee also found that in the area of management of scientists evidence of ineptness with direct impact on quality. Programs for staffing improvement throughout the system were, according to the committee, either grossly inadequate or ineffectively used.[28]

The Agricultural Research Policy Advisory Committee (ARPAC) was established by the Secretary of Agriculture to develop recommendations for policy with respect to planning, evaluating, coordinating, and supporting long-range research programs and delineating the appropriate areas of responsibility of Federal and State agencies in carrying out their programs.

This committee (ARPAC) reviewed the report of the "Pound Committee" and did not feel it appropriate; however, they did believe it to be useful to provide some overview of the general approach taken and the overall perspective that emerged in the report and to provide reactions to the recommendations resulting from the study. ARPAC felt that since the "Pound Report" was generated during a period when large sweeping changes in administrative structures of some of the units of USDA were in the process and significant changes in opportunities for joint planning and program development in SAES and USDA were taking place, the committee could not have taken them into account in its report.

The following is a list of the recommendations by the "Pound Report" in reference to the management of scientists:

1. That the USDA make appropriate changes in its research administration whereby a greater participation in the decision-making process in regard to research would rest with the active researchers and with the lower echelon of administrators who are closest to the programs.
2. That the USDA in the selection of research administrators seek those with an administrative

philosophy that gives maximum encouragement and freedom to the individual scientists consistent with the program mission, and that the mechanism of administration be strengthened so that knowledge of unsatisfactory administrators would be obtained early. This report further recommended that mechanisms be developed for easy replacement of unsatisfactory administrators.

3. That "search screen" by the USDA of the scientific community at large in the selection of its administrators to insure that recruits be the best scientifically available in leadership qualities.
4. The USDA program a greater share of its in-house research on or near campuses of colleges or universities where such programs can benefit from scientific interchange with a broad spectrum of scientists'and can relate to manpower training.
5. That the SAES and USDA provide greater opportunities for post-doctoral training both in terms of post-doctoral experiences for staff and in using their research programs to provide doctoral experiences for others.
6. That the SAES and the USDA give attention to the need for greater integration at the working level

between the agricultural scientists in the basic disciplines.

7. That the USDA strengthen its scientific personnel appointment and review system to include evaluation by the broader scientific community. Administrators since they hold final approval authority, should not serve as chairmen of personnel committees.
8. That the USDA provide increased opportunity for active researchers to advance as researchers to the top salary classifications.
9. That the USDA search the scientific community at large when recruiting for open research positions at all professional grades.
10. That the SAES make greater effort to provide study leave opportunities for their research staff and that both SAES and USDA provide travel funds to enable the staff to attend national and international meetings in their fields. Where necessary, these needs should be placed in high priority competition with other research and training needs.

The Agricultural Research Policy Advisory Committee (ARPAC) and the ARS generally agreed with most of these recommendations but felt that there were certain points that the "Pound Committee" should have considered before making the recommendations.

The ARPAC felt that active researchers can and should make contributions to decision making processes by defining researchable problems, outlining approaches to solutions, assessing feasibility, estimating success probability, and interpreting findings in terms of applicability. Authority at appropriate levels close to programs is desirable to strengthen the partnership relationship. Recent plans for ARS reorganization is a positive step in this direction.

In reference to recommendation number 8---the ARS contends that under the evaluation system of its research scientists positions there is unlimited opportunity for active researchers to advance as researchers to the top salary classification. The NRC Report states that the present Federal system forces scientists to become administrators if they wish to reach the top grades. The ARS felt that this was incorrect and that its scientists are aware that the present system provides for advancement based on research achievements. The ARS goes on to state that as a matter of fact, it has become increasingly difficult to attract top flight researchers in the organization to accept higher level management positions. Most often the reasons cited are their satisfaction with bench research and the realization that they can progress in their present assignment without taking on the burdens of research administrators. Many managerial assignments top out at grade GS-15 and at this level in particular it is extremely difficult to attract bench scientists with managerial capabilities when their own research can take them to this and higher levels. As evidence of bench scientists advancing to top level jobs, ARS pointed out that as of December 31, 1974, it had a total of 37 employees in super-grade and super-grade equivalent positions. Of this number 10 (or over 25%) were bench scientists.

For both FY 1973 and FY 1974 training of ARS scientific personnel is reflected in the following:

	FY 1973	FY 1974
Participants	817	922
Man-Hours of Training	59,042	54,122
Non-Salary Costs of Training	$200,000	$180,000

The ARS did not support the premise in the recommendation "that funds to support an effective program for staff improvement in the USDA be set aside at or above the divisional level before allocations are made for project support." They felt that this recommendation would foster training requests not always related to need.

The USDA does have several programs for training its scientists in and for management. The USDA Graduate School offers many executive development seminars in program management, analysis, and other functions of management. These programs along with the post doctorate graduate school help to combat intellectual erosion and obsolescence.

There is also the issue of should the technical manager have a technical background. Granted that human relations awareness and leadership ability are essential to the science manager's success, should he come from a technical field or can he be a capable all-around administrator who is not qualified in technology?

Rosenthal states that an overwhelming number of commentators on this subject affirm the importance of having a technical staff under the management of technically qualified persons.[30] He goes on to state that in addition to the manager's knowledge of the work itself and of the unique characteristics of scientists and engineers who perform it, a technically qualified manager is more accepted to the group supervised. He cites the following responses from scientific and engineering personnel:[31]

a. Scientists and research engineers want decisions which intimately affect their environment to be in the hands of first-class scientific or technical leadership.

b. Management should know enough about scientific work to provide conditions which permit productive work.

c. Intermediate laboratory managers and supervisors should be competent in technical skills.

Personnel in the ARS felt that the technical manager should have a technical background. A USDA National Program Staff workshop, held on September 18 and 19, 1972, disclosed that some personnel felt that there had not been a clear definition of the Staff role in the new organization. They indicated that the Staff had been delegated broader fields of responsibility, including the maintenance of a national trust to the programs, but relegated to a position of inadequate authority, facilities, and staff assistance. They had no authority to manage scientists or resources and could only function by "moral persuasion." 32

Several personnel assigned to the National Program Staff stated at the workshop meeting that bench scientists felt a loss of accountability to someone from their own discipline and an absence of technical leadership. They felt that administrators, not trained in their discipline, will not be able to relate to them and objectively evaluate their performance for promotional purposes. Some of the small station scientists felt isolated from the national program since they were no longer in direct contact with discipline-oriented supervisors.[33]

Planning and Managing of ARS Programs

The Program Analysis and Coordination Staff (PACS) is primarily concerned with analytical coordinating activities in support of the planning and managing of ARS programs. Analysis involves intensive study of national problems and needs, ARS resources and capabilities to meet these needs, and the alternative approaches and lines of work to follow. Coordination requires developing methodologies, procedures, and related policy for utilizing the special expertise and skills of scientists, research leaders, managers and staff who plan, evaluate, implement, and carry out an effective research program.

Specific functions and responsibilities of the PACS include: developing systems, procedures, and participative approaches to be used throughout the Agency in program planning, evaluation, analysis, coordination, and budget development; coordinating and participating in agencywide program evaluation, technology assessment, and establishment of priorities; coordinating and leading in program analysis and the development of annual budget requests; the coordinating of activities necessary for maintenance of the three-level research project system by which ARS manages its research program, and; conducting research on research management to develop improved criteria, weighting factors, and procedures for establishing priorities. The staff also carries out numerous specific assignments in support of the administrator and associate administrator.

The Staff has developed a number of policy documents on procedures and responsibilities for program planning, evaluation , analysis, and coordination; program direction; program reports; and managing the administrator's contingency and extramural research funds; restructuring the Agency's research planning model consisting of 300 research activities, and planning, implementing, and supporting the ARS system of reviews and workshops designed to give a national overview to program coordination. Also, working closely with the national program staff and others, it has developed numerous special studies and reports in support of the planning, analysis, and management of the Agency's research program.

THE AGRICULTURE RESEARCH SERVICE BUDGET

The annual budget cycle for the ARS generally follows a similar pattern each year. Research opportunities and needs are identified by scientists working with Agency administrators. From these opportunities the highest priority research problems are identified for management decision and consideration in the Department budget. The priority research programs must be of those ARS considered along with other high priority USDA programs.

The Secretary submits his recommendations to the OMB, and their staff presents their recommendations regarding the Department's proposals to the Director and Deputy Director of OMB. These are in turn taken to the President, or whoever represents him in budget matters, and final decisions are made pretty much across the board for the entire Federal Government. It is only after they have gained Presidential approval that they are returned to the Department.

When they come back to the Department, it has limited authority to change any of the numbers that they have given. Obviously, the Secretary participates to a great extent in the whole process. He discusses these matters with the Director of OMB, and hopefully he can persuade him to accept at least some if not all of his research recommendations.

The numbers are given back in considerable detail in about a month, and the Department prints the budget on that basis. That is the process by which USDA prepares its research budget.

From FY 1971 to FY 1976 the budget for the ARS has consistently been increased. Under the regular research appropriations, the ARS proposed for fiscal year 1975 several specific increases which total $16,867,600. This was approximately $20M over the 1974 base funds. However, the end-of-year employment for 1973, 1974, and 1975 remained at a constant figure. See Appendix E.

A review was made of the funds obligated by USDA for agricultural research activities during the three year period, FYs 1970 through 1972. Funds obligated for research represented approximately four percent of the total USDA budget. The ARS obligations averaged approximately $20M increase per year. This has also been true for the subsequent years up to FY 1975. For each of the fiscal years of 1970,1971, and 1972, the ARS accounted for approximately 55 percent of the total USDA research obligations. A breakout of these funds by agency and by area of research for each of the fiscal years 1970 through 1972 is contained in Appendix F.

In 1974 the general economic condition was compounded by inflation. Part of the administration's program to counteract inflation was to hold the line on Federal spending. The impact of this action was felt throughout the USDA including the ARS.

In preparing the FY 1975 Department budget two factors were materially different than in 1974. First, the budget guidelines were less restrictive and secondly, agricultural food supplies were under heavy buying pressure from foreign buyers. These factors contributed to a greater concern for an awareness of the need for agricultural research. Consequently, less stringent constraints permitted requests for increases for agricultural production and marketing efficiency along with several other high priority programs.

Funds for agricultural research have appeared to be stable over the last several years. However, funds for agricultural research in the past fifty years have decreased. In 1924 USDA spent 28 percent of its funds on research and in 1975 only 3 percent of its funds went for research. In 1975 USDA spent 22 percent of its funds on agricultural production; this was one-third of the 66 percent of its funds spent in 1959. The USDA spent 64 percent of its funds in 1975 on social development programs. It is evident that one may conclude that agricultural research is not a top priority at the USDA. Both ERDA and the DHEW spent five times as much on research as did the USDA. See Appendix G for USDA spending by major function for select years.

CONCLUDING REMARKS

Dr. Henry Kissinger, the United States Secretary of State, proposed on his recent trip to Africa a plan to develop the Sahel region of the Sahara Desert for food purposes to feed the people of that region. Is Dr. Kissinger trying to tell the world that it must now feed itself because the United States can no longer do it? If this is what Dr. Kissinger is attempting to convey to the world, he may very well be 100 percent correct.

The United States does not have the surplus food commodities that it once had. All of the best U.S. farm land is now in use. United States farm efficiency in production is known to be the best in the world. Yet, the overall agricultural outlook appears to be in a critical condition. There are those who contend that the USDA has had its day and that its top leadership has become too old, too comfortable, too homogeneous, and unfeeling toward environmental, consumer, and welfare interests.

The USDA research has not been able to make the big technological breakthroughs that it once did. This inability to achieve technological breakthroughs in critical areas is a significant limitation on the expansion of food supplies.

In the case of beef, agricultural scientists have not been able to devise any commercially viable means of producing more than one calf per cow per year. For every animal entering the beef-production process, one adult animal must be fed and maintained for a full year. No breakthroughs in this area appear to be imminent. This would not pose a serious problem if there were a great deal of unused grazing capacity in the world; but unfortunately much of the world's pastureland is already overgrazed, and much more is fully utilized.

Since 1950 soybean yields per acre have increased less than 30 percent while corn yields have increased a remarkable 140 percent. Thus the world gets more soybeans essentially by planting more soybeans. As of 1973, one of every six acres of U.S. farm land was planted to soybeans. As idled cropland disappears in the United States, the inability to achieve a soybean-yield breakthrough may create serious global problems.

To compound the scientific research problem the following specific examples of societal constraints have hampered food production:

1. A number of pesticides that are effective in controlling insect damage to crops and livestock are being removed from the market.

2. Clearance requirements for new pesticides are rigorous enough to escalate costs, and fewer new pesticides are being marketed.
3. Farm waste disposal practices are coming under increasingly heavy restrictions, including the burning of straw and stubble, long considered necessary to control some insects and diseases.
4. Environmentalists and recreationists have actively opposed the use of government lands in the West for grazing. Any substantial loss of such grazing resources would have repercussions on feeder animal production and subsequent beef supplies and prices.
5. Competition for land and water is rising steadily, and several studies predict a drastic decrease in the acreage of irrigated land, especially in the more arid regions.
6. Introduction of new varieties of some plants has recently come under government restrictions.
7. Cars, trucks, homes, and factories release large quantities of air pollutants that reduce yields and concontaminate nearby areas with lead and other poisons.

8. Closures of branch railroad lines and shortages of refrigerated cars and other specialized transport facilities are making the marketing of harvested crops more difficult.
9. Costs of labor, energy, machinery, credit, and other farm inputs are increasing.

While there is no diminution in the level of research in agriculture, agricultural production efficiency is beginning to flatten out. According to the USDA Economic Research Service:

> An extensive inquiry was made into the root causes of productivity change in agriculture. Factors considered were: mechanization, hybridization, fertilization, and pesticides. Change in aggregate agriculture productivity was made a function of changes in adoption of these technologies. There is strong evidence that these few technologies were responsible for the bulk of productivity change during this century. Since most of the technologies (major technologies) were nearly exploited by 1960, the productivity increase slackened since that time. For the future, minor technologies will continue a modest improvement in productivity but major change will have to wait the discovery of new major technology.[34]

However, there are still agriculture research opportunities. The following are some of them:

1. Biomass productivity and utilization.
2. Expanded availability of protein.
3. Genetic engineering.
4. Inorganic chemical nutrient.
5. Lignin properties and utilization.

6. Enzyme research.
7. Satellite survey data acquisition and analysis.
8. Weather forecasting technology development.
9. Weather and climate modification, intended and unintended.
10. Application of systems concepts to agriculture.

I have come to the conclusion from doing this research paper that today's manager of science and scientists cannot rely on the traditional techniques of management and intuitiveness to cope with and solve modern problems. He must think in terms of systems when dealing with technological forecasting, assessment, innovation, and transfer. He should at least take a look at the Limits of Growth by the Club of Rome and the systems dynamics and industrial dynamics techniques and models utilized in this report. Man's future depends upon what he knows about the future at the present time..

The USDA spends only about 3 percent of its budget on research. This may or may not be an adequate amount for its research effort. There are at least five Federal agencies including the Department of Health, Education and Welfare that spent five times as much on research than did the USDA. Cancer research is now receiving more funds than it can adequately utilize, yet there is no significant breakthrough in cancer research.

Agricultural research appears to be in a similar condition. The "Pound Committee" report recommended what I think were some vital changes that the USDA should take into deep consideration and implement toward its total management approach to research. I see the future of agricultural scientific research as being bleak and in need of a second wind.

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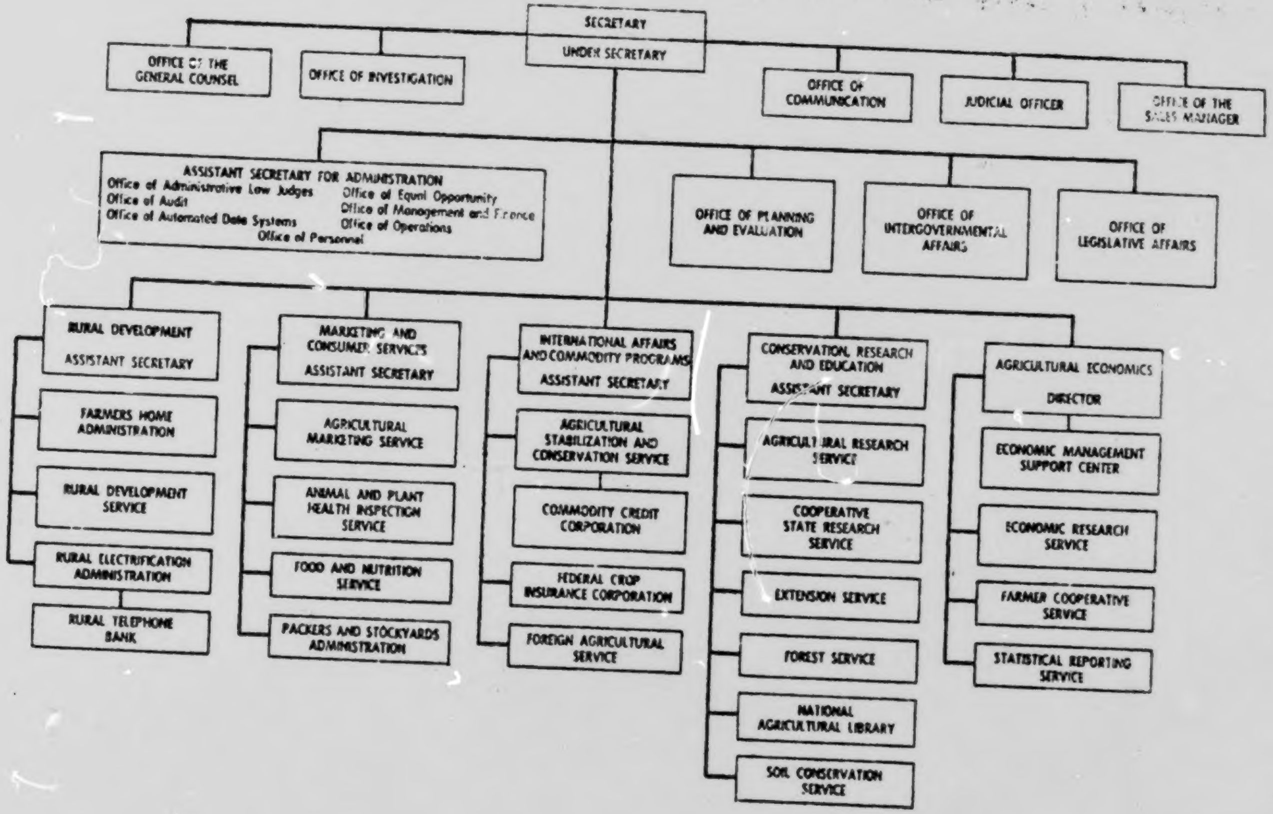
APPENDIX A

DEPARTMENT OF AGRICULTURE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RURAL ELECTRIFICATION ADMINISTRATION
RURAL TELEPHONE BANK
MARKETING AND CONSUMER SERVICES
ASSISTANT SECRETARY
AGRICULTURAL MARKETING SERVICE
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AGRICULTURAL STABILIZATION AND CONSERVATION SERVICE
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FEDERAL CROP INSURANCE CORPORATION
FOREIGN AGRICULTURAL SERVICE
CONSERVATION, RESEARCH AND EDUCATION
ASSISTANT SECRETARY
AGRICULTURAL RESEARCH SERVICE
COOPERATIVE STATE RESEARCH SERVICE
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ECONOMIC RESEARCH SERVICE
FARMER COOPERATIVE SERVICE
STATISTICAL REPORTING SERVICE

APPENDIX B
NINE ACTS OF CONGRESS

1. The Organic Act of 1862 (May 15, 1862)

The Organic Act of 1862, in addition to establishing the Department of Agriculture, authorized the Department to perform a research function in relation to agricultural matters.

2. The Organic Act of 1862 (July 2, 1862)

This Act donated public lands to the states and territories to provide colleges which may benefit agriculture and the mechanic arts. These land grants were made to endow, support, and maintain a course of study related to agriculture and the mechanic arts.

3. The Hatch Act of 1887, as amended (P.L. 84-353)

The original Act established the State Agricultural Experiment Stations for the conduct of original and other research, investigations, and experiments contributing to the establishment and maintenance of an effective agricultural industry. The Secretary of Agriculture is charged with the administration of this Act. As amended in 1955, the Act became the primary source of authorization for the states to conduct agricultural research in connection with, and supported by, the Federal Government. There is a fund matching requirement.

4. The McSweeney-McNary Act of 1928, as amended (P.L. 70-466)

This Act authorized the Department to do research in reforestation and growing, managing, and utilizing timber, forage, and other forest products, maintaining favorable conditions of water flow and the prevention of erosion, protecting timber and other forest growth from fire, insects, disease, or other harmful agents, obtaining the fullest and most effective use of forest lands, and to determine economic considerations which should underlie the establishment of sound policies for managing forest land and utilization of forest products. The Act further provided for the Department to cooperate with other public and private agencies, institutions, and individuals. The Act also authorized the Department to receive money contributions from cooperators to use in research activities.

APPENDIX B CONTINUED

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5. The Research and Marketing Act of 1946, as amended (P.L. 79-732)

This Act gave broad authorization to the Secretary of Agriculture for research into basic laws and principles relating to agriculture and to improve and facilitate the marketing and distribution of agricultural products. The authorization included research to improve the quality of, and the development of, new and improved methods of the production, marketing, distribution, processing, and utilization of plant and animal commodities at all stages from the original producer to the ultimate consumer. The Act further provided authority to conduct research in the areas of human nutrition, development of new uses and markets for agricultural commodities and agricultural resources. The authorization provided for research relating to conservation development and the use of land, forest, and water resources. The Secretary of Agriculture was authorized to enter into contracts with public or private organizations or individuals when in his judgment the research could be carried out more effectively, more rapidly, or at less cost than if performed by Department personnel.

6. The Agricultural Trade Development and Assistance Act of 1954, as amended (P.L. 480)

The Act authorized the sale of agriculture commodities to friendly countries. The amendment authorized the use of foreign currencies accruing from such sales for a variety of research activities, such as developing new markets, disseminating scientific and technological information, and conducting research overseas.

7. Basic Research Grants (P.L. 85-934)

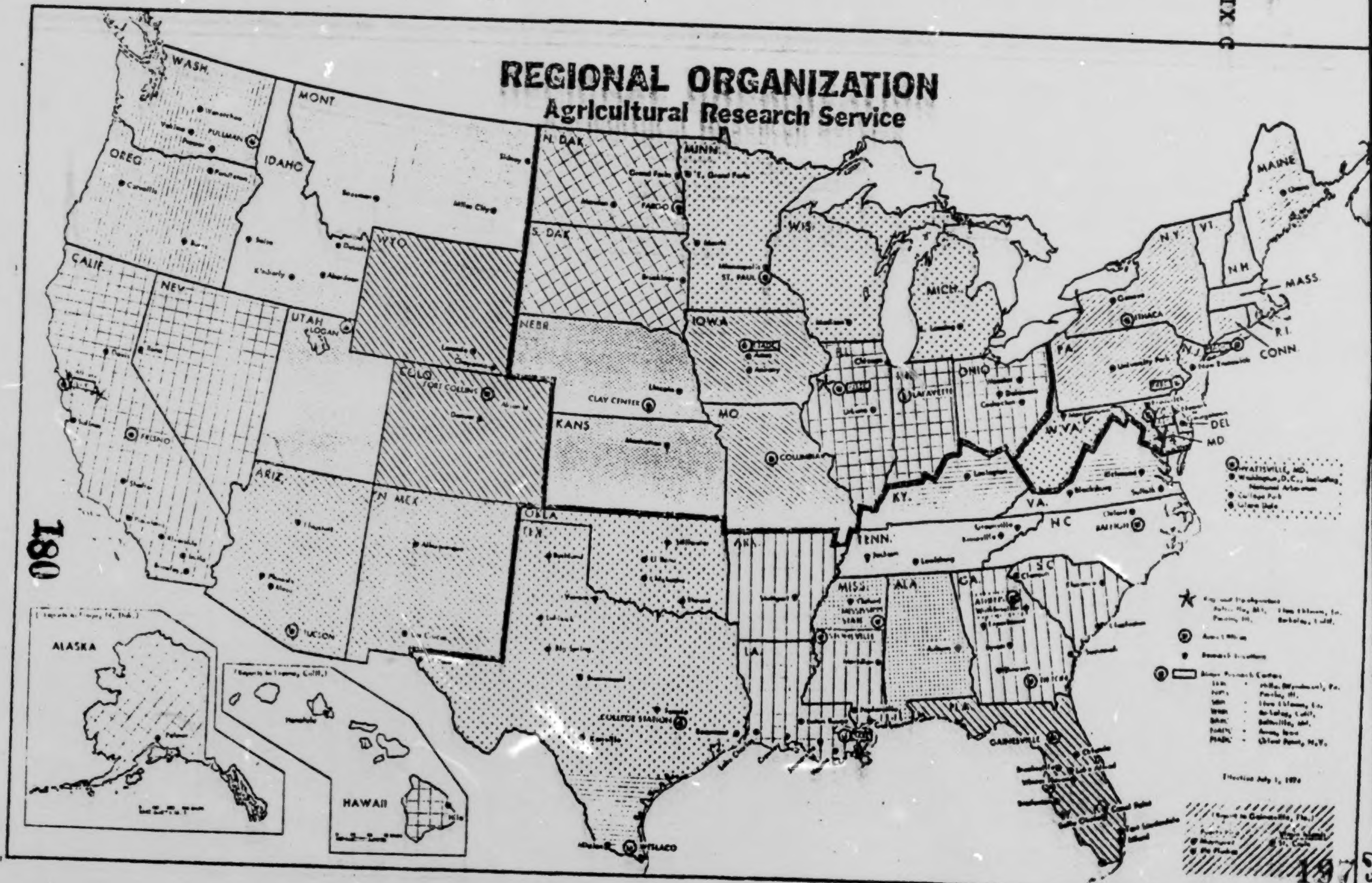
This Public Law authorized Federal agencies to make grants for basic scientific research to nonprofit institutions of higher education or nonprofit organizations whose primary purpose is the conduct of scientific research.

8. The McIntire-Stennis Act of 1962 (P.L. 87-788)

This Act authorized the Secretery of Agriculture to cooperate with the states for the purpose of encouraging and assisting them in carrying out programs of forestry research and to increase scientific competence of foresters through graduate study. All funds must be matched.

9. Special Research Grants (P.L. 89-106)

This Public Law authorized the Secretary of Agriculture to make grants to State Agricultural Experiment Stations, colleges, universities, and other research institutions and organizations and to Federal and private organizations and individuals for basic and applied research to further the programs of the Department.


REGIONAL ORGANIZATION
Agricultural Research Service
WASH.
OREG.
CALIF.
NEV.
IDAHO
MONT.
WYO.
UTAH
COLO.
ARIZ.
N. MEX.
N. DAK.
S. DAK.
NEBR.
KANS.
OKLA.
TEX.
MINN.
IOWA
MO.
ARK.
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WIS.
MICH.
ILL.
IND.
OHIO
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TENN.
MISS.
ALA.
GA.
FLA.
S.C.
N.C.
VA.
W.VA.
PA.
N.Y.
VT.
N.H.
MAINE
MASS.
R.I.
CONN.
N.J.
DEL.
MD.
ALASKA
HAWAII
PULLMAN
LOGAN
FORT COLLINS
FRESNO
TUCSON
CLAY CENTER
ST. PAUL
FARGO
COLUMBIA
LAFAYETTE
ITHACA
RALEIGH
ATHENS
STONEVILLE
COLLEGE STATION
WESLACO
GAINESVILLE
HYATTSVILLE, MD.

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APPENDIX D

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL RESEARCH SERVICE
INFORMATION DIVISION
HYATTSVILLE, MARYLAND 20782

April 6, 1976

Mr. Robert Mitchell
700 Chichaster Lane
Silver Spring, Md. 20904

Dear Mr. Mitchell:

Several documents are enclosed which may be of use to you in your study project that we discussed briefly by phone.

Included is a recent statement that describes how research information gets to the small, part-time farmer and gardener. In general, research information is similarly disseminated to larger, commercial farmers. The larger farmers, however, tend to rely more on direct contact with scientists and trade journals for research information rather than the popular ARS-USDA bulletin. The enclosed copy of recent correspondence on nutrition research covers in some detail how the system works for nutrition information.

The system for communicating research information among scientists is substantially different. It is common practice for scientists to publish the results of their experiments in the many varied scientific journals that are published in our country and internationally. These journals cover many disciplines and are read and cited frequently by scientists who may be doing similar work. ARS scientists on average publish about 3,000 articles annually in various journals. In addition scientists of ARS often attend professional meetings where they present papers and discuss new research with their colleagues. Frequently, these papers are gathered and published as proceedings.

ARS also publishes annually more than 200 technical publications on research; these are made available on request to professional and technical people.

Another means by which scientists keep informed on new research is by subscription to current awareness services such as "SSIE," "CRIS," and the various services provided by NTIS (see enclosed descriptive material).

Finally, since many scientists in specialized disciplines are on a first name basis, they commonly use the telephone to exchange information on new research.

If you wish to pursue this subject further, you might enjoy visiting the National Agricultural Library at Beltsville, Maryland. There you should be able to find additional studies on the dissemination of research information.

I was pleased to learn of your interest in this subject and hope that the enclosed information will be helpful to you.

Sincerely,

Donald K. Childers

Donald K. Childers
Chief, Publications Branch

Enclosures

APPENDIX E

Available Funds and Man-Years 1973 and Estimated, 1974 and 1975

	Actual 1973		Estimated 1974		Estimated 1975	
	Amount	Man-Years	Amount	Man-Years	Amount	Man-Years
Agricultural Research Service:						
Regular Appropriation	a/ $190,881,766	9,191	a/ $188,126,400	9,208	$204,994,000	9,283
Transfer from Section 32 Funds	15,000,000		15,000,000		15,000,000	
Scientific Activities Overseas (Special Foreign Currency Program)	10,000,000	17	5,000,000	16	10,000,000	16
Total	215,881,766	9,208	208,126,400	9,224	229,994,000	9,299
Deduct allotments to other agencies	-976,657	-32	-995,000	-33	-1,003,000	-33
Net	214,905,109	9,176	207,131,400	9,191	228,991,000	9,266
Reimbursements from other USDA Appropriations:						
Animal and Plant Health Inspection Service - emergency programs and field station services	2,563,944	100	2,778,800	144	2,789,300	144
Food and Nutrition Service - improved dietary nutrition	165,065	10	235,800	16	236,700	16
National Agricultural Library-various services	48,118	2	428,600	9	430,300	9
Soil Conservation Service - field station services	17,289	--	69,100	--	69,100	--
Coordinated Departmental Services	80,879	3	31,400	1	31,500	1
Miscellaneous activities ..	41,590	2	78,200	1	78,500	1
Total other USDA appropriations ..	2,916,885	117	3,621,900	171	3,635,400	171

APPENDIX E CONTINUED

Item	Actual 1973		Estimated 1974		Estimated 1975	
	Amount	Man-Years	Amount	Man-Years	Amount	Man-Years
Total, Agricultural Appropriation Bill	217,821,994	9,293	210,753,300	9,362	232,526,400	9,437
Working Capital Fund	6,198,290	322	1,017,000	--	--	--
Other Federal Funds	3,685,361	141	4,870,400	137	4,591,400	137
Non-Federal sources	532,832	17	697,700	20	749,200	20
Total, Agricultural Research Service	228,238,477	9,773	217,338,400	9,519	237,867,000	9,594

End-of-Year Employment:	1973 Actual	1974 Estimated	1975 Estimated
Permanent Full-time	8,495	8,275	8,275
Other	1,129	1,400	1,400
Total included in ceiling	9,624	9,675	9,675
Number of disadvantaged youth	450	400	400
Total	10,074	10,075	10,075

a/ Excludes $2,000,000 reappropriation.

APPENDIX F

VI. USDA FUNDS OBLIGATED FOR AGRICULTURAL RESEARCH

A review was made of the funds obligated by the USDA for agricultural research activities during the three-year period, FYs 1970 through 1972. Funds obligated for research represented approximately four percent of the total USDA budgets. The breakout of these funds by agency and the National Agricultural Library for each of the fiscal years was as follows:

	Fiscal Years		
	1970	1971 (in thousands)	1972
Agricultural Research Service	$158,812	$171,237	$188,410
Cooperative State Research Service	62,584	69,507	82,816
Forest Service	45,590	48,752	54,140
Economic Research Service	14,881	15,934	15,356
Farmer Cooperative Service	953	1,018	1,069
Statistical Reporting Service	689	720	741
National Agricultural Library	208	391	228
TOTALS	$283,717	$307,558	$344,020

For each of the respective fiscal years, the ARS accounted for approximately 55 percent of the total USDA research obligations. A breakout of the ARS obligations by area of research for each of FYs 1970 through 1972 is as follows:

	Fiscal Years		
	1970	1971 (in thousands)	1972
Farm Research			
Animal Science	$ 10,513	$ 11,673	$ 12,663
Veterinary Science	16,038	17,295	18,849
Plant Science	34,360	36,467	40,105
Entomology	20,422	21,966	26,762
Soil and Water Conservation	19,120	20,561	22,175
Agricultural Engineering	7,376	8,175	8,638
TOTALS	$107,829	$116,142	$129,192

(Continued)

APPENDIX G

USDA SPENDING BY MAJOR FUNCTION*, FOR SELECTED YEARS

	1924[1]	1932[2]	1940[3]	1951[4]	1959[5]	1969[6]	1975[7]
Administration	2%	1%	**	**	**	**	**
Research	28	18	5	9	3	4	3
Production	—	—	28	41	66	39	22
Consumer-Marketing-Regulatory	**	1	1	1	1	1	3
Social Development	—	—	26	37	9	9	64
Conservation	—	—	38	4	2	2	2
International	—	—	—	—	17	40	3
Forestry	13	7	3	6	3	4	3
Weather Bureau	2	1	**	—	—	—	—
Roads	27	66	—	—	—	—	—
Other	29	6	**	1	**	**	**
Totals	101%	100%	101%	99%	101%	99%	100%

*Agencies were placed by major function, with subdivisions within agencies which have more than one major function (all subdivisions are indicated in the footnotes). Agencies classified wholly as social development are Farm Security Administration, Farmers Home Administration in 1969 and 1975, Rural Electrification Administration, Food and Nutrition Service, and rural areas development agencies. The research category includes all research-oriented agencies and Extension. The international category includes the Foreign Agricultural Service and all allocations under P. L. 480 and technical assistance.

Amounts used were estimates of current fiscal year's expenditures, as printed in the U. S. Government's *Budget* for the next fiscal year.

**Less than .5%.

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1. *Message of the President of the United States Transmitting the Budget for the Service of the Fiscal Year Ending June 30, 1925* (Washington, D.C.: U.S. Government Printing Office, 1923), pp. 81-262. (Amount appropriated for fiscal 1924, total: $111,868,043 including $29,773,480 for cooperative road-building.)
2. *Message of the President of the United States Transmitting the Budget for the Service of the Fiscal Year Ending June 30, 1933* (Washington, D.C.: U. S. Government Printing Office, 1931), pp. A32-A47. (Estimated expenditures for fiscal 1932, total: $333,547,300.)
3. *The Budget of the United States Government for the Fiscal Year Ending June 30, 1941* (Washington, D.C.: U. S. Government Printing Office, 1940), pp. A39-A47. (Estimated expenditures, 1940, total: $1,348,196,468.) Conservation includes $475 million allocated for "conservation and use of agricultural land resources," most of which was allocated in payments to producers.
4. *The Budget of the United States Government for the Fiscal Year Ending June 30, 1952* (Washington, D.C.: U. S. Government Printing Office, 1951). pp. 344-351. (Estimated expenditures, general and special funds for fiscal 1951, total: $1,322,532,491.) The following budgets were distributed among two or more functions: Agricultural Adjustment Administration and Production and Marketing Administration.
5. *The Budget of the United States Government for the Fiscal Year Ending June 30, 1960* (Washington, D.C.: U. S. Government Printing Office, 1959), pp. 320-325. (Estimated expenditures for 1959, total: $7,341,363.) The following budgets were distributed among two or more functions: Agricultural Marketing Service and Commodity Credit Corporation.
6. *The Budget of the United States Government, Fiscal Year 1970* (Washington, D.C.: U. S. Government Printing Office, 1969), pp. 221-243. (Estimated expenditures for fiscal 1969, total: $7,650,271 plus $4,474,623 for P. L. 480 special assistance and special export.) The following agency budgets were divided among two or more functions: Consumer Marketing Service and Commodity Credit Corporation.
7. U. S. Congress, House, Committee on Appropriations, *Agriculture and Related Agencies Appropriations for 1976, Hearings*, before a subcommittee of the Committee on Appropriations, House of Representatives, 94th Cong., 1st Sess., 1975, Part 1, Table 4, pp. 153-160. (New budget authority, estimates for fiscal 1975 including parenthetical allocations, totals: $14,414,400,000 plus $9,290,100,000 in parenthetical allocations.

SCIENCE AND TECHNOLOGY ADMINISTRATION AT THE ENVIRONMENTAL PROTECTION AGENCY

by

Alexander C. Bartko

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INTRODUCTION

The basic mission of the Environmental Protection Agency(EPA) is to protect the public health by maintaining and enhancing environmental quality in a way consistent with other national goals. Organizational functions which are characteristic of EPA's mission include: setting and enforcing environmental standards; researching the causes, effects and control of environmental problems; disseminating information on environmental problems and solutions; demonstrating how to protect and enhance the environment; and providing technical assistance in solving environmental problems.[1]

Within the research and development area, EPA's role is that of a science and technology administrator for the benefit of the public welfare. This paper provides an assessment of EPA's execution of science and technology policy in the public management of science. Several factors are discussed in order to assess agency policy formulation to achieve national goals. These factors include: 1) Fiscal planning, 2) Decision making, 3) Innovation, 4) Technology assessment, 5) Regulatory process, 6) Political institutional relationships, and 7) Resource management. The final chapter of this paper provides conclusions about agency performance relative to its policy goals.

CHAPTER I

EXECUTIVE ORGANIZATION FOR ENVIRONMENTAL ACTIVITIES

The basis for involvement of the Federal government in environmental matters is the National Environmental Policy Act of 1969, public law 91-190 of January 1, 1970.[2] The purposes of the Act are:

1. To declare a national policy which will encourage productive and enjoyable harmony between man and his environment
2. To promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man
3. To enrich the understanding of the ecological systems and natural resources important to the Nation
4. To establish an organization concerned with the environment within the executive office--designated as the Council on Environmental Quality.

The Environmental Protection Agency(EPA) was created through an executive reorganization plan to consolidate certain Federal government activities into a single agency. The plan(Reorganization Plan No. 3 of 1970) was sent by the President to Congress on July 9, 1970, and EPA was established as an independent Agency in the Executive Branch on December 2, 1970.[3] The roles and functions of EPA are as follows:

1. The establishment and enforcement of environmental standards consistent with national environmental goals
2. The conduct of research on the adverse effects of pollution and on methods and equipment for controlling it; the gathering of information on pollution and the use of this information in strengthening environmental protection programs and recommending policy programs

3. Assisting others through grants, technical assistance and other means in arresting pollution of environment

4. Assisting the Council on Environmental Quality in developing and recommending to the President new policies for the protection of the environment.[4]

The relationship between EPA and the Council on Environmental Quality(CEQ) is planned to be analogous to that which existed between the Office of Science and Technology(OST) and major R&D agencies.[5] CEQ, like OST prior to its abolishment, is a unit in the Executive Office of the President, and plays a key role in advising the President and acting in his behalf to coordinate activities, and to help develop policies and priorities in its program area. CEQ is concerned with all environmental activities, which included wildlife, preservation, parklands, land use and population growth. Although EPA's programs in pollution control and abatement activities, represent 77 percent of the total expected outlays in fiscal year 1977, twenty other agencies reported budget authority and outlays in this same category.[6]

EPA has day-to-day operating responsibilities in the area of standard setting and certain related research, enforcement, and assistance activities concerning pollution control. CEQ and EPA are complementary organizations and work closely together in order to achieve overall strategies and objectives.

CHAPTER II

ENVIRONMENTAL PROTECTION AGENCY

ORGANIZATION

The Environmental Protection Agency is headed by an Administrator, who is supported by a Deputy Administrator and five Assistant Administrators (see Chart 1). Three of the Assistant Administrators are responsible for activities which cut across all programs and are "functional" managers. These activities are planning and management, enforcement, and research. The other two Assistant Administrators are responsible for media or pollutant basis subjects; e.g., water pollution, air pollution, solid waste, etc. The media activities are primary policy development; standards and criteria development; and support and evaluation of regional activities. The Office of Research and Development is organized as shown on Chart 2.

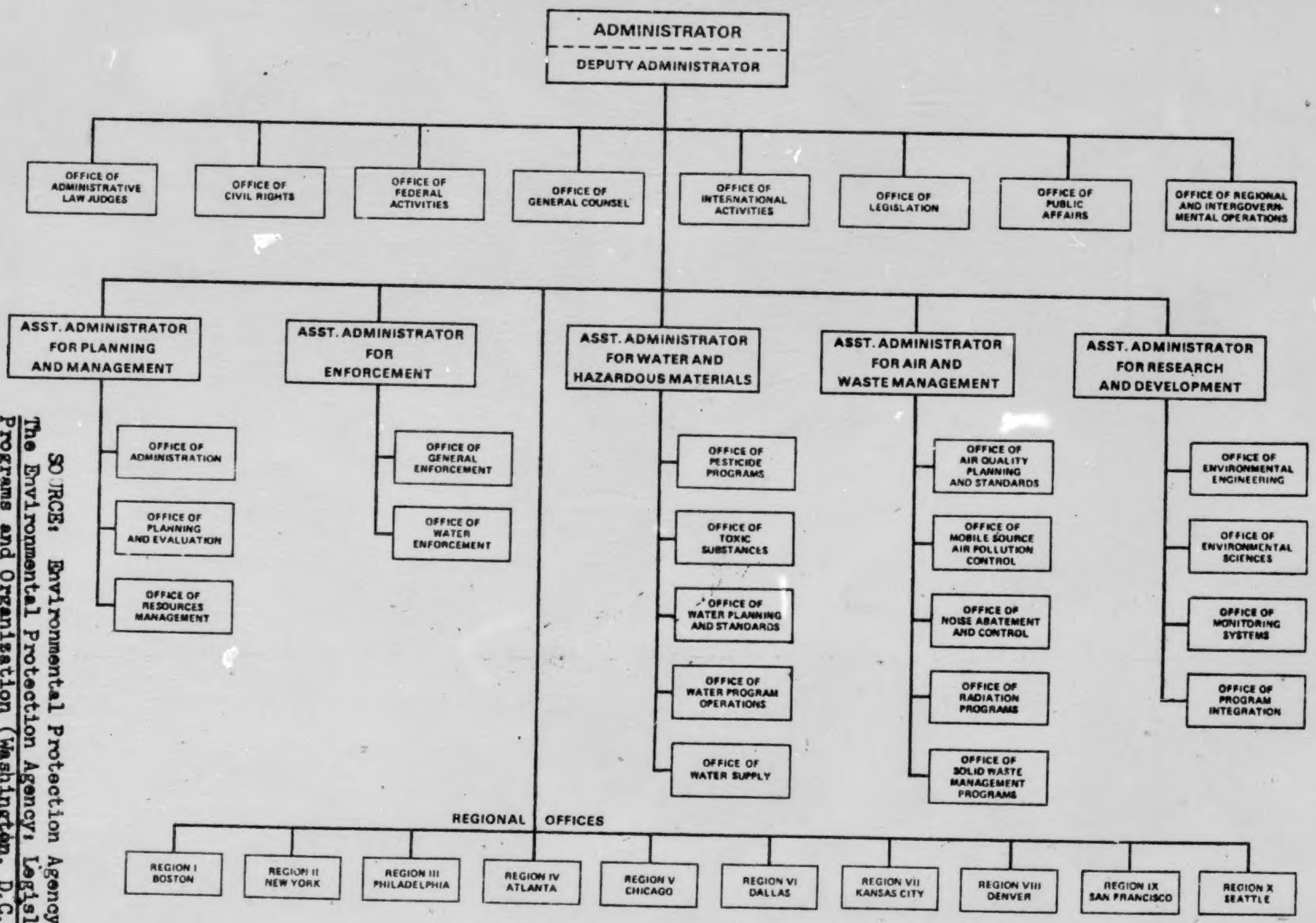
The laboratory organization is categorized by five systems. They are as follows:

1. Regional Laboratories reporting to Regional Administrators
2. Pesticide Laboratories reporting to the Assistant Administrator for Water and Hazardous Materials
3. Radiation Monitoring and Motor Vehicle Emission Laboratories reporting to the Assistant Administrator for Air and Waste Management
4. National Field Investigation Centers reporting to the Assistant Administrator for Enforcement and General Counsel
5. National Environmental Research Centers reporting to the Assistant Administrator for Research and Development.[7]

EPA officials have pointed out that there has been a lack of

Chart 1

U. S. ENVIRONMENTAL PROTECTION AGENCY


ADMINISTRATOR
DEPUTY ADMINISTRATOR
OFFICE OF ADMINISTRATIVE LAW JUDGES
OFFICE OF CIVIL RIGHTS
OFFICE OF FEDERAL ACTIVITIES
OFFICE OF GENERAL COUNSEL
OFFICE OF INTERNATIONAL ACTIVITIES
OFFICE OF LEGISLATION
OFFICE OF PUBLIC AFFAIRS
OFFICE OF REGIONAL AND INTERGOVERNMENTAL OPERATIONS
ASST. ADMINISTRATOR FOR PLANNING AND MANAGEMENT
OFFICE OF ADMINISTRATION
OFFICE OF PLANNING AND EVALUATION
OFFICE OF RESOURCES MANAGEMENT
ASST. ADMINISTRATOR FOR ENFORCEMENT
OFFICE OF GENERAL ENFORCEMENT
OFFICE OF WATER ENFORCEMENT
ASST. ADMINISTRATOR FOR WATER AND HAZARDOUS MATERIALS
OFFICE OF PESTICIDE PROGRAMS
OFFICE OF TOXIC SUBSTANCES
OFFICE OF WATER PLANNING AND STANDARDS
OFFICE OF WATER PROGRAM OPERATIONS
OFFICE OF WATER SUPPLY
ASST. ADMINISTRATOR FOR AIR AND WASTE MANAGEMENT
OFFICE OF AIR QUALITY PLANNING AND STANDARDS
OFFICE OF MOBILE SOURCE AIR POLLUTION CONTROL
OFFICE OF NOISE ABATEMENT AND CONTROL
OFFICE OF RADIATION PROGRAMS
OFFICE OF SOLID WASTE MANAGEMENT PROGRAMS
ASST. ADMINISTRATOR FOR RESEARCH AND DEVELOPMENT
OFFICE OF ENVIRONMENTAL ENGINEERING
OFFICE OF ENVIRONMENTAL SCIENCES
OFFICE OF MONITORING SYSTEMS
OFFICE OF PROGRAM INTEGRATION
REGIONAL OFFICES
REGION I BOSTON
REGION II NEW YORK
REGION III PHILADELPHIA
REGION IV ATLANTA
REGION V CHICAGO
REGION VI DALLAS
REGION VII KANSAS CITY
REGION VIII DENVER
REGION IX SAN FRANCISCO
REGION X SEATTLE

SOURCE: Environmental Protection Agency, The Environmental Protection Agency: Legislation, Programs and Organization (Washington, D.C.: Environmental Protection Agency, 1976), p. 11.

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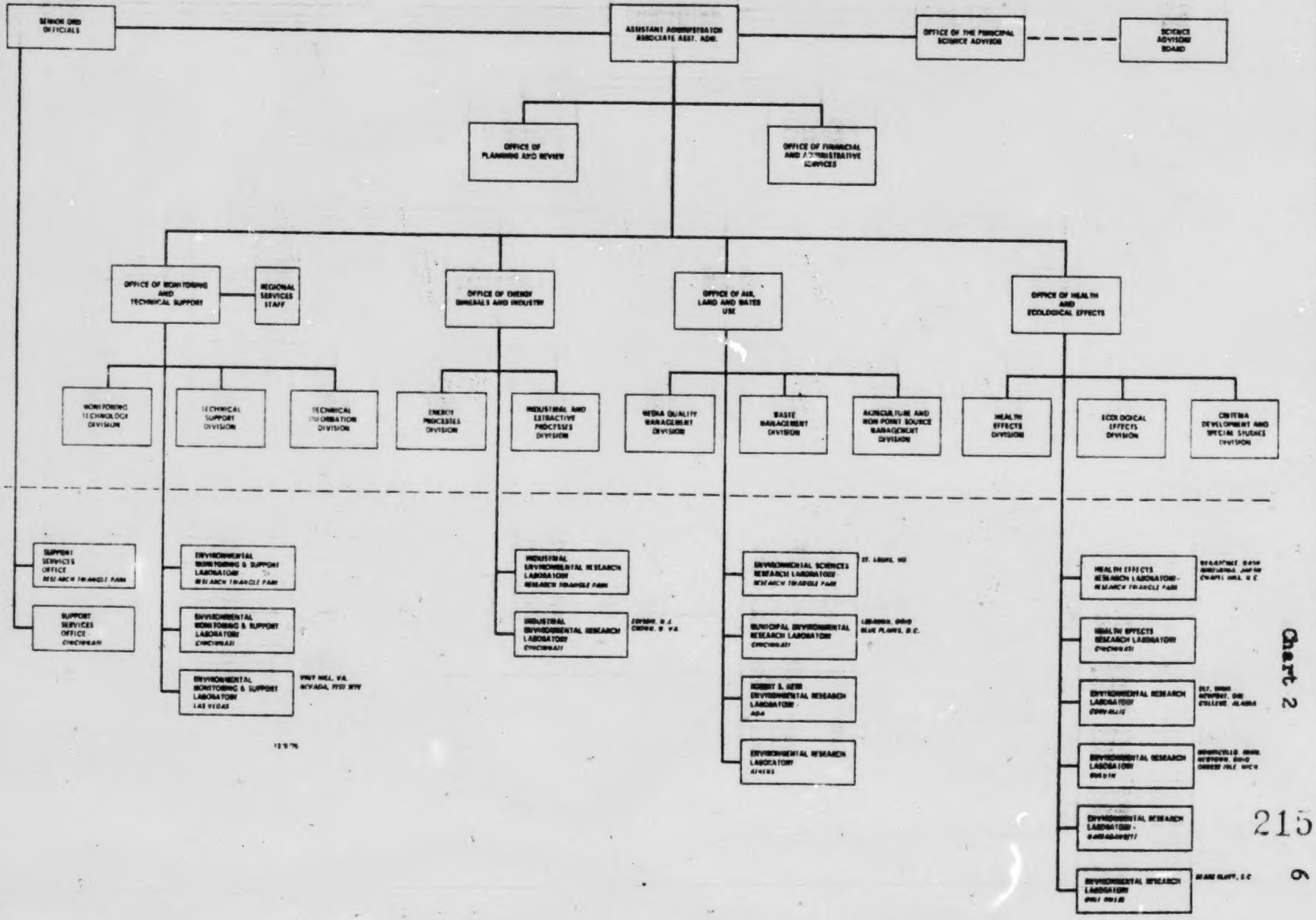
U.S. ENVIRONMENTAL PROTECTION AGENCY
OFFICE OF RESEARCH AND DEVELOPMENT


SENIOR ORD OFFICIALS
ASSISTANT ADMINISTRATOR ASSOCIATE ASST. ADM.
OFFICE OF THE PRINCIPAL SCIENCE ADVISOR
SCIENCE ADVISORY BOARD
OFFICE OF PLANNING AND REVIEW
OFFICE OF FINANCIAL AND ADMINISTRATIVE SERVICES
OFFICE OF MONITORING AND TECHNICAL SUPPORT
REGIONAL SERVICES STAFF
OFFICE OF ENERGY MINERALS AND INDUSTRY
OFFICE OF AIR, LAND AND WATER USE
OFFICE OF HEALTH AND ECOLOGICAL EFFECTS
MONITORING TECHNOLOGY DIVISION
TECHNICAL SUPPORT DIVISION
TECHNICAL INFORMATION DIVISION
ENERGY PROCESSES DIVISION
INDUSTRIAL AND EXTRACTIVE PROCESSES DIVISION
MEDIA QUALITY MANAGEMENT DIVISION
WASTE MANAGEMENT DIVISION
AGRICULTURE AND NON-POINT SOURCE MANAGEMENT DIVISION
HEALTH EFFECTS DIVISION
ECOLOGICAL EFFECTS DIVISION
CRITERIA DEVELOPMENT AND SPECIAL STUDIES DIVISION
SUPPORT SERVICES OFFICE RESEARCH TRIANGLE PARK
SUPPORT SERVICES OFFICE CINCINNATI
ENVIRONMENTAL MONITORING & SUPPORT LABORATORY RESEARCH TRIANGLE PARK
ENVIRONMENTAL MONITORING & SUPPORT LABORATORY CINCINNATI
ENVIRONMENTAL MONITORING & SUPPORT LABORATORY LAS VEGAS
VINT HILL, VA. NEVADA, TEST SITE
INDUSTRIAL ENVIRONMENTAL RESEARCH LABORATORY RESEARCH TRIANGLE PARK
INDUSTRIAL ENVIRONMENTAL RESEARCH LABORATORY CINCINNATI
EDISON, N.J.
ENVIRONMENTAL SCIENCES RESEARCH LABORATORY RESEARCH TRIANGLE PARK
ST. LOUIS, MO
MUNICIPAL ENVIRONMENTAL RESEARCH LABORATORY CINCINNATI
LEBANON, OHIO BLUE PLAINS, D.C.
ROBERT S. KERR ENVIRONMENTAL RESEARCH LABORATORY ADA
ENVIRONMENTAL RESEARCH LABORATORY ATHENS
HEALTH EFFECTS RESEARCH LABORATORY RESEARCH TRIANGLE PARK
CHAPEL HILL, N.C.
HEALTH EFFECTS RESEARCH LABORATORY CINCINNATI
ENVIRONMENTAL RESEARCH LABORATORY CORVALLIS
NEWPORT, ORE. COLLEGE, ALASKA
ENVIRONMENTAL RESEARCH LABORATORY DULUTH
MONTICELLO, MINN. NEWTOWN, OHIO GROSSE ILE, MICH
ENVIRONMENTAL RESEARCH LABORATORY NARRAGANSETT
ENVIRONMENTAL RESEARCH LABORATORY GULF BREEZE
BEARS BLUFF, S.C.
12/9/75

SOURCE: Office of Research and Development, Environmental Protection Agency, Program Guide Fiscal Year 1976 (Washington, D.C.: Environmental Protection Agency, March, 1976), p. 64.

Chart 2

consolidation of laboratory systems, which resulted from bringing fifteen separate governmental units together when EPA was formed.[8] Laboratory administrative responsibility is fragmented among the ten Regional Administrators and four or five Assistant Administrators at the Central Office.[9] According to some present and former EPA officials, there should be no more than two laboratory systems(regulatory and research and development), and there should be a formal procedure for active coordination of all laboratories, not just blocks on an organizational chart showing conceptual relationships.[10]

Further contributing to a lack of coordination are some Assistant Administrators, who frequently are not as interested in utilization of facilities as in programs they can obtain or develop in their laboratory system.[11] Also, the organizational structuring of program planning and evaluations is under the Assistant Administrator for Planning and Management, being the only Assistant Administrator with no laboratories within his organization.[12]

Recommendations have been made to solve organizational problems. One considers placing the research management responsibilities that currently reside at the National Environmental Research Center administrative level, directly at the laboratory level.[13] Another is to reorganize the headquarters staff, in order to provide only one tier of management between the Assistant Administrator for Research and Development and the laboratory directors.[14]

CHAPTER III

FISCAL POLICY

Federal environmental programs are classified in three broad categories: pollution control and abatement; understanding, describing and predicting the environment; and environment protection and enhancement activities.[15] Federal funding for environmental R&D programs are almost evenly distributed between pollution control and abatement acitivites and programs relating to understanding, describing, and predicting the environment.[16] Total Federal funding for R&D programs related to environment improvement will reach an estimated $1,468.6 million in 1977.[17] This represents an increase of 26 percent over actual 1975 outlays of $1,162.2 million and an increase of 3 percent over 1976 funding levels of $1,430 million.[18]

In fiscal year 1976, the environment function claimed 4.6 percent of the total Federal R&D obligations, which was $21.7 billion.[19] According to the National Science Foundation, the growth in funding for the environment has been steadily upward from 1969 to 1976 averaging 17 percent per year, and the share of environment within the Federal R&D total has risen from 2.1 percent to 4.6 percent in that timespan.[20] Growth in environment research has represented increased interest and support by Congress.

Research and development programs will account for some 38 percent ($280 million) of the EPA's operating budget, which excludes construction grants.[21] R&D program trends within nineteen program elements are illustrated in Table I. Energy-related environmental control is the highest

TABLE I

R&D PROGRAM TRENDS
(Dollars in Millions)

	1972	1973	1974	1975	1976
Environmental Health					
Air quality effects research	5.4	10.7	2.1	18.5	18.2
Energy-related environmental effects	-	-	-	17.0	17.5
Interdisciplinary effects research	3.9	3.3	3.1	3.2	4.5
Water supply effects research	-	1.4	2.1	3.4	3.9
Pesticides effects research	1.8	2.0	2.0	2.3	3.9
Water pollution effects research	1.3	0.1	-	1.2	2.9
Radiation effects research	1.6	2.0	1.2	1.7	1.1
Toxic substances effects research	-	-	-	0.2	0.3
Noise effects research	-	0.2	0.4	0.4	0.1
Pollution Control and Environmental Protection					
Energy-related environmental control	-	-	17.6	103.6	116.9
Water quality control	45.4	52.3	57.6	57.8	52.9
Air quality control	48.2	63.6	51.6	43.0	37.7
Interdisciplinary studies	3.4	10.0	14.4	13.8	13.6
Water supply control	-	0.7	0.8	1.4	9.2
Pesticides control	2.2	3.1	7.6	9.5	8.7
Solid waste management	7.7	30.7	7.0	6.2	6.5
Toxic substances research	-	-	-	1.9	2.0
Radiation protection	1.3	0.4	1.6	1.2	0.8
Noise abatement	0.1	0.1	0.2	0.2	-

SOURCE: National Science Foundation, An Analysis of Federal R&D Funding by Function (Washington, D.C.: Government Printing Office, August, 1975), p. 65.

priority program by level of funding, although they were initiated as recently as 1974. The purposes of these programs include: protection of human health, welfare, and the ecosystem; implementation of energy system alternatives; facilitation of the use of domestic energy supplies; development of cost-effective control technologies; and assessment of environmental implications of energy conservation measures.[22]

For future R&D program priorities, Table II shows resource plans for the five-year period FY-1976 through FY-1980. Options A and B assume that the total resources for FY-1977 and beyond will remain at the FY-1977 level. Option A shows the resources needed for control technology R&D, if the goals of the Federal Water Pollution Control Act(FWPCA) are to be more closely met by industrial dischargers.[23] In order to meet FWPCA goals, tradeoffs in other program areas are shown in Option A. Option B trades off the increase for industrial pollution control technology R&D(shown in Option A) for increases in water supply, monitoring and technical support, and health and ecological effects research.[24] According to the Office of Research and Development, the funding plan shown in Table II does not reflect a level of resources sufficient to fully perform all anticipatory research and development, to allow getting a headstart on newly emerging problems, or on improving the quality of existing abatement and monitoring methods and environmental quality and effects data.[25]

TABLE II

OFFICE OF RESEARCH AND DEVELOPMENT PROJECTED RESOURCE NEEDS
(Dollars in Millions)

Program Area	FY-75	FY-76	FY-77	FY-78	FY-79	FY-80
Energy/Environment						
Projected	134	100	96	118	121	120
Option A	(134)	(100)	(96)	(84)	(80)	(85)
Option B	(134)	(100)	(96)	(90)	(90)	(90)
Health and Ecological Effects						
Projected	64	72	67	88	90	92
Option A	(64)	(72)	(67)	(56)	(55)	(64)
Option B	(64)	(72)	(67)	(69)	(69)	(69)
Industrial Processes						
Projected	23	20	20	54	60	32
Option A	(23)	(20)	(20)	(54)	(60)	(32)
Option B	(23)	(20)	(20)	(16)	(16)	(16)
Public Sector Activities						
Projected	28	30	28	37	37	38
Option A	(28)	(30)	(28)	(20)	(19)	(27)
Option B	(28)	(30)	(28)	(32)	(31)	(31)
Monitoring and Technical Support						
Projected	19	27	27	35	37	37
Option A	(19)	(27)	(27)	(24)	(24)	(30)
Option B	(19)	(27)	(27)	(31)	(32)	(32)
Other(R&D Program Support and Management						
Projected	9	7	7	7	8	8
Option A	(9)	(7)	(7)	(7)	(7)	(7)
Option B	(9)	(7)	(7)	(7)	(7)	(7)
TOTAL						
Projected	277	256	245	339	353	327
Option A	(277)	(256)	(245)	(245)	(245)	(245)
option B	(277)	(256)	(245)	(245)	(245)	(245)

NOTE: Figures do not include agency program management costs charged against R&D appropriation

SOURCE: Office of Research and Development, U.S. Environmental Protection Agency, U.S. Environmental Protection Agency Environmental Research Outlook FY 1976 through 1980 (Washington, D.C.: Environmental Protection Agency, February, 1976), pp. 16-18.

CHAPTER IV

DECISION MAKING

Decision making in research and development involves: policy, program planning and management, contracting and grant awards, the advisory process, and interest group roles.

Policy

The policy for research and development at EPA is contained primarily in nine separate Acts of Congress. Table III shows the most relevant sections of the Acts giving authorizations to EPA's research and development programs. The major theme for research and development is the "control, prevention, abatement, effects" of pollution.[26] Research and development objectives and priorities are established in response to the overall mission and priorities of EPA and are highly mission-oriented, concerned with solving specific priority problems rather than only advancing scientific knowledge.[27]

Overall research strategies for providing results, that are directly useful to environmental decision-makers, regulatory officials and polluters; include the following:

1. Emphasis is given to research designed to protect human health
2. A balance must be maintained between immediate technical support and continuing information needs and longer-term research to meet future problems
3. Resources should be reserved for short-term technical support
4. Dissemination of technical information and technology transfer

Table III Authorizing Legislation for EPA Program

Legislation	General R&D Authorization	Sections
Clean Air Act (CAA)	The Clean Air Act, as amended, directs the Administrator to establish a national research and development program for the prevention and control of air pollution and shall conduct, and promote the coordination and acceleration of research investigations and experiments relating to the causes, effects, extent, prevention, and control of air pollution.	103, 104, 108, 109, 111, 112, 119, 202, 211, 303, 312, 313
Federal Water Pollution Control Act (FWPCA)	The 1972 amendments establish research programs for the prevention, reduction, and elimination of pollution in navigable waters of the United States. Specifically, the agency must render technical advice, and conduct research, investigations, experiments, training, demonstrations, surveys, and studies; establish advisory committees to evaluate research progress and proposals; establish a water quality surveillance system to monitor the quality of navigable waters and initiate studies measuring the social and economic costs and benefits of water pollution control activities. The Administrator must establish field laboratories and research facilities, investigate the harmful effects of pollutants on the health and welfare of persons, and make a comprehensive study of the pollution of the Great Lakes. Oil spills and thermal discharge must be investigated. A major research development and demonstration effort is required to develop control technology and management methods necessary to eliminate the discharge of pollutants into waterways.	
Safe Drinking Water Act, (SDWA)	The Administrator may conduct research, studies, and demonstrations relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments of man resulting directly or indirectly from contaminants in water, or to the provision of a dependably safe supply of drinking water.	Sec. 1442, 1444
Solid Waste Disposal Act, (SWDA)	This Act directs the Administrator to conduct and cooperate research efforts relating to any adverse health and welfare effects of the release into the environment of material present in solid waste, and methods to eliminate such effects; the operation and financing of solid waste disposal programs; the reduction of the amount of such waste and unsalvageable materials; the development and application of new and improved methods of collecting and disposing of solid waste and processing and recovering materials and energy from solid wastes.	204, 205, 208

Table III (Cont.)

Legislation	General R&D Authorization	Sections
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	The Administrator shall undertake research to carry out the purposes of the Act, giving priority to the development of biologically integrated alternatives for pest control. The Administrator shall formulate a national plan for monitoring pesticides and undertake activities in support of it.	20, 27
Public Health Service Act (PHSA)	The Administrator, under the Public Health Service Act, has authority to determine levels of radiation in the environment, their pathways to man, and the health risks from these doses. EPA is cooperating in a study of health effects of radiation along with monitoring the environment (particularly around nuclear power plants) to calculate the population's total exposure to various forms of radiation. EPA is also conducting a complete review of present radiation standards, along with an assessment of the entire nuclear fuel cycle.	301
Noise Control Act (NCA)	This law enables the Administrator to establish a comprehensive research program in the area of noise. Sucha a program enables EPA to undertake the necessary investigations into the health effects of noise under varying conditions of magnitude, duration, background, etc. Such information is currently lacking in most areas. This program examines those technological aspects of noise control and abatement not currently being treated.	Sec. 14, 19
Marine Protection, Research and Sanctuaries Act (MPRSA)	The Administrator in coordination with the Secretary of Commerce and the Coast Guard shall initiate a comprehensive and continuing program of monitoring and research regarding the effects of the dumping of material into the ocean water or waters which ebb or flow into the Great Lakes and report the effects not less frequently then annually. The Administrator is responsible for offering consultation to the Secretary of Commerce on the possible long-range effects of pollution, overfishing and man-induced changes of ocean ecosystems.	201, 202
National Environmental Policy Act (NEPA)	The National Environmental Policy Act October of 1969 (NEPA) requires Federal Agencies to prepare environmental impact statements (EIS) for legislative proposals and for other "major federal actions that significantly affect the quality of a human environment." In preparing these EIS's, a Federal agency must consult with other agencies having jurisdiction by law or special expertise over such environmental considerations. Since EPA's purview is the total environment, it must be consulted for most EIS's.	102(2)(C)

SOURCE: Office of Research and Development, Environmental Protection Agency, U.S. Environmental Protection Agency Environmental Research Outlook FY 1976 through 1980 (Washington, D.C.: Environmental Protection Agency, February, 1976), p. 12, 13.

should be addressed

5. An adequate program for pollution monitoring and measurement activities must be maintained

6. Environmental management methods and technology development and demonstration should attempt to:

   a. Stimulate, assess and support development of technically and economically feasible technological solutions, including control technology(e.g., stack gas scrubbers); substitution of alternative, more environmentally acceptable processes and practices(e.g., biological pest controls); and materials and conservation measures(e.g., recycling)

   b. Improve management techniques to enhance environmental quality through nonstructural and nontreatment methods, requiring reduced capital costs(e.g., change farming methods)

   c. Use institutional approaches to promote technological options (e.g., improve regulatory approaches, provide economic incentives or sanctions, etc.)

7. Costs, energy usage and undesirable transfer of pollutants should be minimized in solving environmental problems

8. Assessments that allow risks, benefits and costs to be compared in guiding decisions will continue to be supported

9. Analytical tools for evaluating control strategies should be developed

10. Flexibility must be maintained to address unforseen problems.[28]

Program

The planning responsibility for research and development programs is within four offices of the Office of Research and Development. They are as follows:

1. The Office of Monitoring and Technical Support
2. The Office of Health and Ecological Effects
3. The Office of Energy, Minerals, and Industry
4. The Office of Air, Land, and Water Use.[29]

In all phases of the planning process, research and development activities are grouped into five major program and several subprogram areas.[30] The major program areas are shown in Table II. Planning responsibility for subprograms is generally in one office, while implementation responsibility is often the responsibility of several offices. Establishing specific major objectives, relative priorities, and resource levels is "planning responsibility," while "implementations responsibility" refers to developing an approach to each objective and supervising the required work.[31]

Project

Projects are accomplished by:

1. Inhouse research and development by EPA scientists and engineers
2. Extramural grants and contracts with educational institutions, private insustry, research institutes, state and local governments
3. Interagency agreements with other Federal agencies.[32]

In fiscal year 1976, about 25 percent of research and development funds were planned for inhouse activities, with 55 percent for grants and contracts and 20 percent for interagency agreements.[33] Table IV shows the amount of extramural R&D funds compared to total R&D resource level by program area for fiscal year 1976.

The Office of Research and Development(ORD) publishes a program guide to:

1. Acquaint the R&D community with the organizational structure of ORD
2. Make public the extramural research program objectives for a given fiscal year
3. Provide general guidelines necessary when developing grant or contract applications.[34]

In the guide, each research program is summarized in the form of "Accomplishment Plans," which describes a specific research objective designed to meet a specific Agency goal.[35] The guide encourages contact with the cognizant

TABLE IV

EXTRAMURAL R&D FUNDS
COMPARED TO TOTAL R&D FUNDING FOR FISCAL YEAR 1976

Program Area	Total	Extramural	Percent of Program Total
1. Energy Program	100	54.5	54.5%
2. Health and Ecological Effects	72	24.4	33.9%
3. Public Sector Activities	30	18.8	62.7%
4. Industrial Processes	20	14.5	72.5%
5. Monitoring and Technical Support	19	5.5	28.9%
6. Other	7	-	-
Total Funds for Fiscal Year	256	117.7	46% for FY

SOURCES: Office of Research and Development, U.S. Environmental Protection Agency, U.S. Environmental Protection Agency Environmental Research Outlook FY 1976 through 1980 (Washington, D.C.: Environmental Protection Agency, February, 1976), p. 16; and Office of Research and Development, U.S. Environmental Protection Agency, Program Guide Fiscal Year 1976 (Washington, D.C.: Environmental Protection Agency, March, 1976).

Laboratory Director for all grant projects.

Formal grant applications are reviewed for program relevance by the cognizant Labaratory Director. Scientific/technical merit reviews are conducted by both inhouse and extramural experts. Extramural reviews are by the National Science Foundation method--individual reviews submitted by mail.[36] Also, comments are obtained from the Regional Office in the region where the applicant is located and where the project would be conducted to determine the relationship of the proposed project to regional programs and policies.[37] The cognizant Laboratory Director coordinates the scientific/technical merit review, assembles and evaluates both intramural and extramural review comments, and prepares a recommendation for action on the proposal. Recommendations may include awarding a grant, rejecting the application, or attempting to negotiate a change in the scope of work to more directly meet research objectives.

Public Advisory Process

The administration of environmental regulation programs implies great needs for outside scientific advice on a broad range of issues. Central to consultative functions is the Science Advisory Board(SAB), whose major objectives are as follows:

1. To provide an independent source of advice and appraisal of scientific goals, needs, and research programs
2. To form a channel of direct communication between top management and senior members of the extramural scientific community
3. To provide a comprehensive capability to assist key program managers in applying science to the solution of specific issues.[38]

Recently, a reorganization of SAB was instituted, moving the board from the Office of Research and Development(as shown on Chart 2) to the Immediate Office of the Administrator.[39] The purpose of the change was to provide more comprehensive functional SAB committee coverage. The board, as orginally constituted, consisted of seven ad hoc advisory committees coordinated by an Executive Committee of SAB.[40] Ad hoc committees will continue to be used in order to provide a forum for public interest groups.[41]

The committees of the Science Advisory Board and some of their functions are as follows:

1. Environmental Health Advisory Committee
   - a. Reviews, on request from the Administrator, the health research activities of the Agency; concerning problems, issues, and scientific policies
   - b. Annual review of R&D efforts and progress within the Agency and related efforts outside the Agency
   - c. Maintains cognizance of on-going inhouse and extramural research
   - d. Conducts reviews of on-going research grant and contract projects
   - e. Advises on the standard setting process for pollutants concerned with public health.[42]
2. Ecology Advisory Committee
   - a. Recommends to the Assistant Administrator for Research and Development(Principal Science Advisor) needed R&D activities and priorities
   - b. Reviews annual and projected research work plans related to program objectives, feasibility, and performance factors to avoid duplication of effort within and outside of the Agency (Reviews include on-site observation of existing or proposed programs or projects)[43]
3. Environmental Measurements Advisory Committee
   - a. Reviews overall environmental measurement activities of the Agency for the Administrator
   - b. Advises on establishing monitoring standards.[44]
4. Environmental Pollutant Movement and Transformation Committee
   - a. Advises the Administrator on policy and programs relating to movement and transformation of pollutants in various media
   - b. Peer review of research and development in the movement and transformation of pollutants.[45]

5. Technology Assessment and Pollution Control Advisory Committee

    a. Advises the Administrator on Agency policy and programs relating to technology assessment and pollution control

    b. Predicts and assesses future changes in technological systems (production, municipal, transportation, agricultural, communication, energy, etc.)that will effect pollution control methods and relates the analysis to current Agency decisions

    c. Assesses national capabilities to research, develop, demonstrate, and apply pollution control techniques; and recommends ways to use capabilities to meet the needs for pollution control techniques.[46]

The composition of committee membership is variable, with no more than fifteen members from science, engineering, and management. Members are appointed by the Administrator for overlapping terms of one to four years. It is important to note that a stipulation was made that no member of the Ecology Advisory Committee shall be an employee of the Federal Government.[47]

CHAPTER V

INNOVATION

Innovative Process

Innovation is a set of activities--a process which transforms ideas, concepts, or scientific and technological potential, into commercially available and useful products, processes, or techniques.[48] Useful processes may be considered as those which contribute to protecting or enhancing environmental quality. When the forces of regulation and government sponsored research and development are combined, pollution control and abatement technology is stimulated. Within this framework, the Environmental Protection Agency may be thought of as being "innovative."

Polluting industries generally lack technical competence to comply with pollution regulations for several reasons.[49] Control of pollution often involves application of technology foreign to the polluting industry(e.g., the chemical processes now being applied to the utility industry). New technology cannot be developed in a short period of time. Many companies are too small to maintain research capabilities. In larger companies, research is devoted almost exclusively to work or problems they are best equipped to handle. Compared with expenditures in other research areas, expenditures to improve pollution control capability may be minimal.

Examples of innovation are found within the EPA flue gas desulfurization(FGD) program.[50] Research is being directed to understand and apply the unique chemistry of an installation at the Louisville Gas and Electric

Company to other installations. A Wellman-Lord regenerable FGD test program at coal-fired utility sites has been proven reliable and effective on oil-fired units in Japan and will be demonstrated on a full-scale unit. Test programs for regenerable FGD systems will provide data for evaluation as will supporting studies involving by-product marketing and waste-water utilization from FGD systems. Data generated from FGD research and development is expected to be given to regulatory groups and user industries through the technology transfer program.

Certain authorizations and constraints must be recognized in the scope of research programs at EPA.[51] Among these are legislative authorizations and mandates. Research activities are directed to control, prevent, and abate pollution effects. Also, specific authorizations, or even mandates relate research work on specific problems(e.g., acid mine drainage, lake restoration, etc.,) or direct certain special types of funding for eligible grantee or contractor organizations. There are other mandates for R&D that derive from implementation dates for major environmental protection standards and regulations. The effects of all these requirements force a concentrated R&D effort and limit innovative potential for basic research.

Another factor to be recognized is that the research program within EPA is essentially at the same level, both in funding and in personnel, as it was when EPA was created in 1970.[52] The rest of the Agency has grown dramatically as new programs have been established, but the research organizations have been under pressure to provide money and people to meet programmatic requirements.

Technology Transfer

Before the creation of EPA, technology transfer programs for the environment started as a consequence of the Federal Water Pollution Control Act(FWPCA).[53] With large investments($15-18 billion) being made in construction grants for municipal waste-water systems, concern was expressed for the design technology being used in new systems. City consultant engineers tended to be conservative in their design approach in order to minimize costs and risks. To promote advanced treatment methods, a small technology transfer program(approximately 3-4 manyears and ¼ million dollars) was initiated to market new technologies to target audiences.

EPA's technology transfer program grew from the municipal FWPCA technology program. It expanded into industry, in order to provide plant managers with financial strategies for extracting usable chemical pollutants to minimize control technology costs both within industry and municipalities.

Environmental quality technology transfer programs are "soft," in that technological analytics(e.g., quality control manuals) are involved. Passive and active approaches are used in technology transfer. Passive programs involve publishing data(e.g., waste treatment process brochures tailored to local decision makers' needs). The brochures explain in basic terms how to evaluate technical alternatives posed to local decision makers by technical experts. Examples of active technology transfer are found in a lecture series presented to an urban consortium of decision making officials. Seminars are conducted on land treatment, advanced waste treatment, industrial pollution control, monitoring of industrial wastewater, water treatment processes and analytical weights and measures.

The philosophy of the technology transfer program is to avoid taking a regulatory position, whereby technology consumers are directed to accomplish an action. Technology transfer provides alternatives for what can be done by providing information in front of decision officials and designers. The objective of the technology transfer program is to effectively impact the construction, installation, and operation of pollution control and abatement facilities, to ensure that the latest viable technologies are transferred to potential users, and eliminate the possibly large investment in obsolete facilities.[54]

The Technology Transfer Staff is located within the Office of Monitoring and Technical Support and consists of eleven employees. The staff has been relocated to the National Environmental Research Laboratory in Cincinnati, Ohio. The technology transfer program is still relatively small. In fiscal year 1975, the program budget was $1.25 million.[55]

The Technical Information Division of the Office of Research and Development is responsible for evaluating information flow for technology transfer and providing means to get information to technology consumers.[56] Technology users consist of three major groups:

1. Consultants, municipal, industrial and state design engineers
2. Administrative decision makers with pollution control responsibilities
3. The general public and special-interest environmental and conservation groups.

The compilation and dissemination of information in the form of publications is a major effort in the technology transfer program.

Types of publications being prepared and disseminated by the Technical Information Division include the following:

1. Design manuals intended for pollution control facility design engineers (The manuals include information such as theory, design criteria, identification of key parameters, cost experience, equipment, characteristics, and available experience and case histories)
2. Technical Capsule Reports, which describe specific industrial pollution control projects

3. Seminar publications covering information presented at design seminars
4. Handbooks to cover non-design technical subject areas, such as monitoring, lab procedures, and operations
5. Process brochures prepared for administrative decision makers and conservation groups to briefly familiarize them with new waste treatment processes
6. Technology transfer newsletters for keeping interested parties informed of program activities.[57]

Patent Policy

Patent policy is important in the technology transfer process. A potential competitive advantage provides an incentive to invest in research and promote return on investment by transfering the technology to commercial applications. The issuance of patent rights to extramural contractors and agency personnel also serves as an incentive to innovate by attracting the best R&D performers.

Patent rights may be titled, licensed or deferred. EPA has a strict title policy concerning patent rights.[58] This policy claims all patent rights for the Federal Government, when research and development work is funded by the Agency.

CHAPTER VI

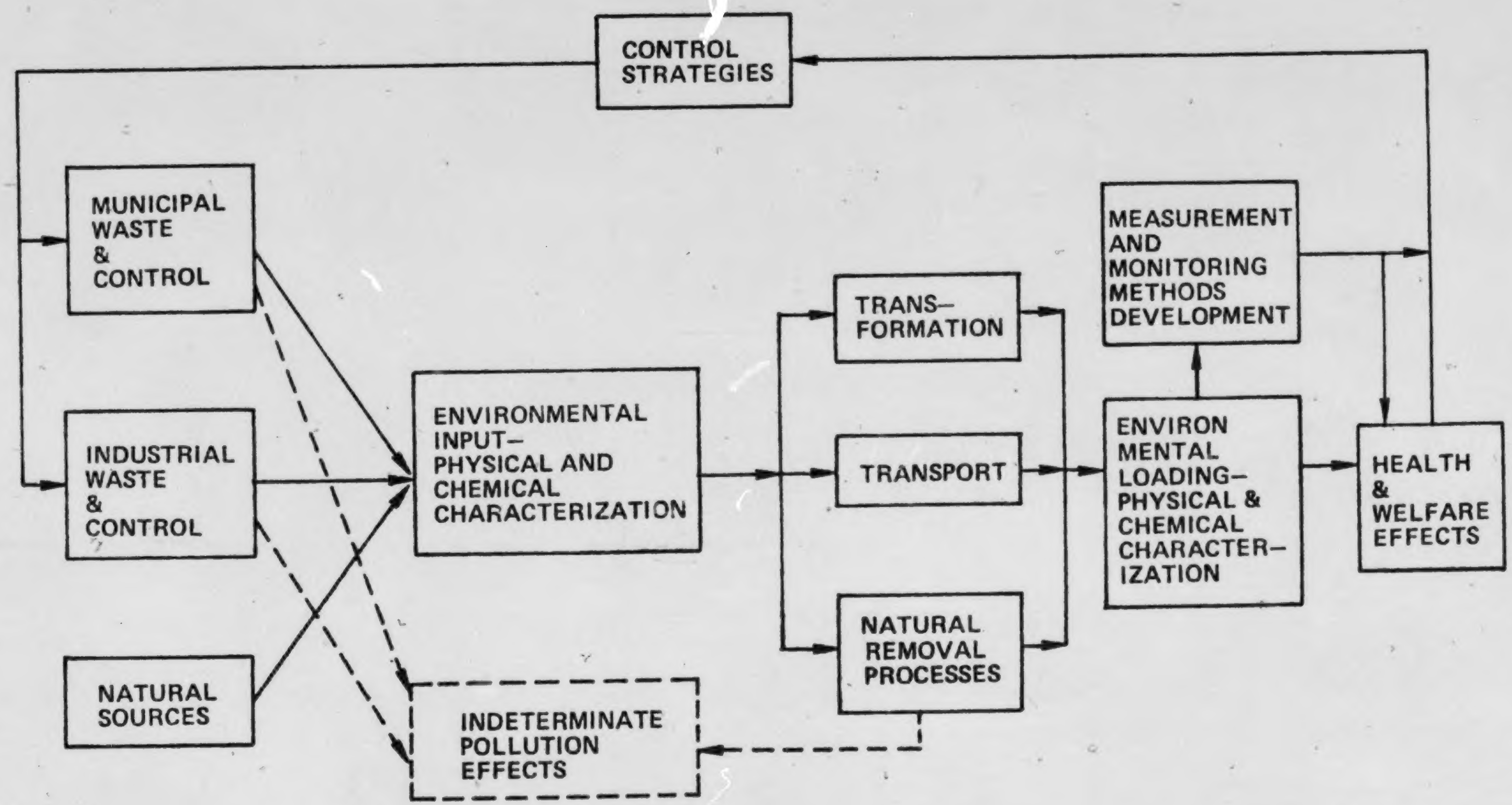
TECHNOLOGY ASSESSMENT

Technology assessment is; "A class of policy studies in which systems examine the effects on society that may occur when a technology is introduced or modified; with a special emphasis on consequences that are unintended, indirect or delayed."[59] Technology assessment is used at EPA as a basis for EPA regulatory policies and is the objective of all research and development programs.

The total R&D effort may be described as an interconnected system as shown in Figure 1. The environment loading element includes natural and man-made "sources." Emissions and wastes from each source are characterized by physical and chemical properties in source process inputs and outputs. Environment loadings are subject to physical and chemical transformation, transport and removal processes. These interactions are assessed and must be understood for efficient control of pollutants. From the viewpoint of health, ecological, and other welfare effects, concentrations of environmental contaminants are assessed. Located within the effects element are reversible and irreversible effects of exposure from contaminants.

Technology and environment-related assessments are addressed by EPA by means of the environmental impact statement. The policy for preparation of environmental impact statements is to use the process to explore alternative actions that will avoid or minimize adverse impacts and to evaluate both long and short range implications of proposed actions to the

Figure 1. FLOWCHART OF ENVIRONMENTAL R&D


CONTROL STRATEGIES
MUNICIPAL WASTE & CONTROL
INDUSTRIAL WASTE & CONTROL
NATURAL SOURCES
ENVIRONMENTAL INPUT– PHYSICAL AND CHEMICAL CHARACTERIZATION
INDETERMINATE POLLUTION EFFECTS
TRANS– FORMATION
TRANSPORT
NATURAL REMOVAL PROCESSES
MEASUREMENT AND MONITORING METHODS DEVELOPMENT
ENVIRON MENTAL LOADING– PHYSICAL & CHEMICAL CHARACTER– IZATION
HEALTH & WELFARE EFFECTS

SOURCE: Office of Research and Development, Environmental Protection Agency, U.S. Environmental Protection Agency Environmental Research Outlook FY 1976 through 1980 (Washington, D.C.: Environmental Protection Agency, February, 1976), p. 21.

environment.[60] Execution of this policy is ensured by the National Environmental Policy Act of 1969, which requires that any project that uses Federal funds or a Federal permit must be approved for environmental considerations before work commences. The Administrator of EPA must comment in writing on the environmental impact of any matter relating to his duties and responsibilities, and refers to the Council on Environmental Quality any matter that the Administrator determines is unsatisfactory from the standpoint of public health, welfare or environmental quality.[61] As an example, EPA criticized a study of nuclear accident risks by the Atomic Energy Commission for underestimating the number of likely deaths and illnesses from a catastrophic reactor failure.[62]

Several long-term problems, associated with energy conservation, are expected for regulatory and enforcement components of EPA. Within the energy program area, concentrated technology assessment research is being conducted. The Conservation Utilization and Technology Assessments Subprogram is funded in fiscal year 1976 by $26,819,000 for extramural programs.[63] It includes three distinct parts.[64] The conservation part will provide environmental assessments and contribute to the development of environmentally compatible advanced technologies and control technologies for waste recovery, indoor air quality, and second generation energy systems--e.g., solar and geothermal energy. The utilization part includes the identification, characterization, assessment and development of control technology for pollutants associated with electric utility and industrial combustion sources. The objective of the integrated assessment part is the identification of environmentally, socially and economically acceptable alternatives for meeting National energy supply objectives, and assistance in the selection of optimum policies for the attainment of associated environmentally quality goals.

7

CHAPTER VII

REGULATORY PROCESS

Formulation of standards and regulations for pollution abatement and control is one of the Environmental Protection Agency's most important responsibilities. The process has direct and indirect relations to the management of science. Regulation implies scientific progress in knowledge concerning the unintended effects of pollution and the development of technology for control of pollution.

Agency Procedures

Authorization to establish regulation standards or requirements is contained in environmental statutes passed by Congress. The procedural framework within which regulation takes place is specified by legislation, which provides a wide variation in discretion delegated to EPA. But, if it is unspecified, procedures must c[illegible]ply with the minimum standards of fairness set forth in the Administrative Procedures Act.

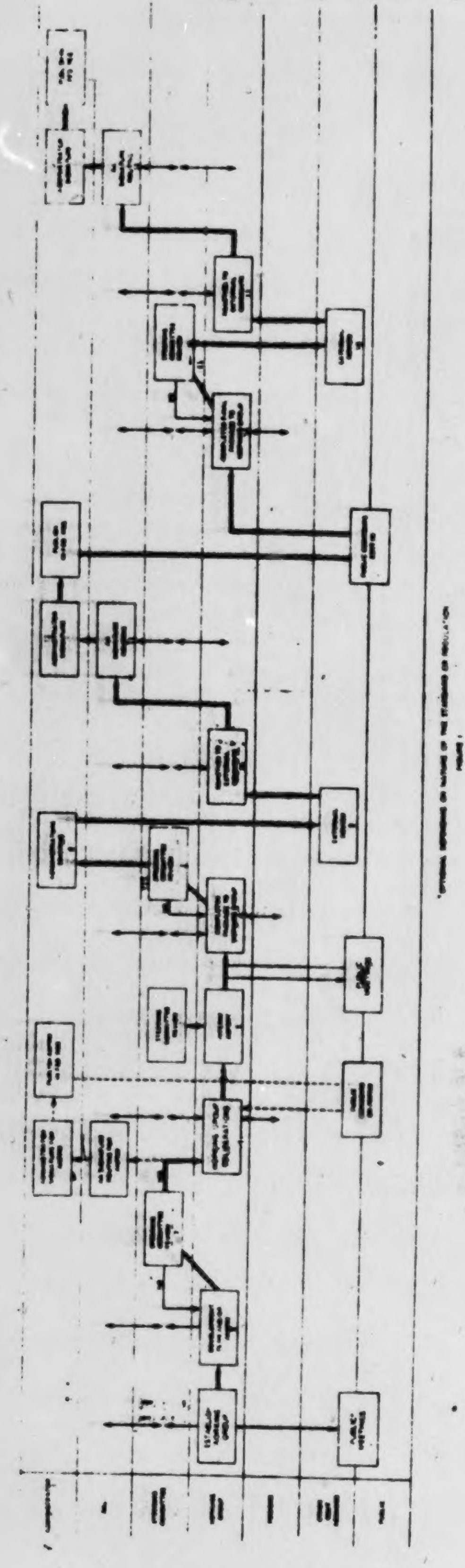
The mechanics of establishing regulations is directed in the manual entitled, "Procedures for the Standards and Regulations Development Process," issued by the Office of Planning and Management on December 6, 1974.[65] A flow chart showing the levels of review and events for regulation formulation is shown in Figure 2. The major milestones for the standard-setting process are as follows:

Proposed Rulemaking

a. Formation of the Working Group

Figure 2

Regulatory Review Cycle



SOURCE: Office of Planning and Management, U.S. Environmental Protection Agency, Procedures For the Standards and Regulations Development Process (Washington, D.C.: Environmental Protection Agency, December 6, 1975), p. 38.

b. Approval of the Development Plan and Advanced Notice of Proposed Rulemaking

c. Draft Package Delevered to Working Group

d. Interim Report Delivered to Working Group

e. Final Package to Working Group

f. Final Package Completes Steering Committee Review

g. Review by Administrator

h. Request External Comments

    1. Receive external comments

    2. Start external coordination(discuss regulation and comments with OMB)

    3. Complete external coordination

    4. Submit to Administrator for Signature

i. Publish Proposed Standard in the *Federal Register*

Final Rulemaking

j. End of Public Comment Period

k. Final Modified Package to Working Group

l. Final Modified Package Completes Steering Committee Review

m. Review by Administrator

n. Request external comments

    5. Receive external comments

    6. Start external coordination

    7. Complete external coordination

    8. Submit to Administrator for signature

o. Publication of Final Standard in *Federal Register*.[66]

There are several levels of responsibility and different groups involved in preparing regulations.[67] The day to day operations for assembling a regulatory package are accomplished by the Working Group. Working Group deliberations include arranging for letting of contracts, and conducting any necessary original scientific or economic analysis. A Steering Committee oversees the development of all standards and regulations and provides Agency review below the Assistant Administrator. Review consists of discussion of key policy issues, resolving issues, and calling attention to issues where higher level guidance is needed. Technical and scientific issues not resolved in the Working Group are also discussed.

A completed proposed regulatory package includes the following elements:

1. The draft regulation, Notice of Proposed Rulemaking, or Guidance, or Report to Congress
2. The Administrator's Action Memorandum, which describes the package, the issues addressed, and the consequences of the proposed action
3. Voluntary Environmental Impact Statement for appraising the public of the effects of major standard-setting actions, if required.[68]

Copies of the approved package are sent to other Federal agencies having an interest in the standard.

The Notice of Proposed Rulemaking is published in the Federal Register for a formal public comment period, which is normally between 30 and 60 days, depending upon the complexity of the matter or the legislative mandate. At the close of the public comment period, the Working Group reconvenes to review received comments and modify the proposal appropriately. The action memorandum is then expanded to indicate the nature and disposition of major comments received and changes made in the regulatory package. Once again, the package is circulated for review by other interested Federal agencies. A Final Rulemaking package is then circulated among interested Assistant Administrators for approval. The final package is then submitted to the Administrator for final review and approval. Once approved, the Final Rulemaking package is published in the

Federal Register. After the review process cycle is repeated, the rule-making package becomes a Final Standard. The Final Standard then has force of law, after publication.

Regulatory Decision-Making

The previous procedure is only a limited portion of the total information gathering and decision-making framework encompassing EPA's responsibilities. The procedure described does not attempt to relate how the information and data base needed to make the indicated decisions flow into and through the process.

Two relatively distinct levels or categories of decision-making exist within EPA. Top-level decision makers generally determine or influence the outcome of regulatory actions in three ways:

1. By setting broad policy direction for Agency programs
2. By reviewing and approving standards and regulations, which establish the criteria for specific lower-level decisions
3. By the adjudication of cases which are appealed to the head of the Agency for final disposition, prior to judicial intervention.

The second level involves the application of "decision rules" established by top-level decision makers. This level encompasses the vast majority of regulatory decisions such as the issuance of discharge permits, registration of pesticides, or specifying emmission levels for sources of air pollution.

The National Academy of Sciences(NAS) has attempted to construct a more complete description of the information-gathering and decision-making process of the Agency as they believe it should be designed. The process incorporates several elements which NAS believes do not currently exist in the Agency for the systematic dissemination of: (a), hazards, costs, and benefits information; (b), feedback information; and (c), feed-forward information.[69]

For hazards, costs, and benefits information, data-gathering techniques should include the following:

1. Identification of the types of hazards presented by potentially toxic substances
2. Determination of minimum data needed to assess hazard potentials
3. Development of a priority system for obtaining specific hazard data on a continuing basis
4. Assignment of responsibility for developing data as between government agencies and the private sector
5. Establishment of techniques to validate generated data.[70]

Decisions for crisis problems characteristically have not been subjected to adequate feedback information techniques.[71] Crisis problems involve high costs of control, political ramifications, and high public visibility, tending to take on overtones of finality once the immediate conflict has been resolved and the issue fades from public attention. The Administrator should make public the information base for decisions in major cases. Gaps or weaknesses in the information and data base should be clearly identified, and steps should be taken to provide for feedback information.

Specific assessment should be ensured for future information needs associated with regulatory options, as the options are being considered for a given problem.[72] Feed-forward information is generated by this procedure as well as feedback data to construct a more complete and validated data base.

Another recommendation made by NAS concerning the regulatory process is political accountability.[73] In a mixed technical and sociopolitical problem situation, a "white paper" should be published, describing in detail the rationale used in reaching a given decision.

NAS also suggests considering extensions of the Science Advisory

Board's current authority.[74] If the Science Advisory Board(SAB) felt that the technical analysis in a given situation was inaccurate or misleading and should be revised before any decision is made, it should report this to the decision maker. If the SAB's recommendation is disregarded, the decision maker should be forced to include an explanation of this action in the public record. However, NAS recognizes the importance of carrying out scientific peer review with a clearly defined role and responsibility. An advisory board cannot develop an advocacy position because political decisions cannot be made without political accountability.

Effects of Regulation

As mentioned previously, well-formulated regulations provide incentives to develop control technologies. However, regulations may tend to discourage R&D or force it into less than optimal directions. Disincentives to new R&D may occur under any of the following circumstances:

1. Technology is marginal or not available to meet established regulations(Since probability of success is high for challenging the regulation, R&D will not be stimulated)
2. Supporting data for regulations is inadequate
3. Excessive costs are needed to comply with certification or registration procedures(For example, fewer petitions may be received to establish tolerances for new pesticides, because the cost of data collection adds excessively to the cost of new product development. Potential benefits are not accorded proper weight to enjoy positive aspects of innovation)
4. Regulations are expected to be changed, superseded, or to be weakly enforced(For example, the automible industry delayed R&D for emmission control until it became clear that stringent standards would be maintained and enforced)
5. Moving targets(Moving control targets established by regulation, make it attractive for industry to focus R&D on the distant target and avoid working on near term requirements)
6. Inadequate time alloted for orderly R&D
7. Non-uniform application of regulations

8. Inadequate attention to intermedia effects(A data base in support of a regulation must include a description of acceptable means for treating secondary pollution caused by control of primary pollution).[75]

CHAPTER VIII

POLITICAL INSTITUTIONAL RELATIONSHIPS

The responsibilties for a successful research and development program for environmental enhancement and protection are divided among three formal levels of government in the United States: Federal, State, and local (county or city). Each level has discrete as well as shared activities.

In the initial sections of the Solid Waste Disposal Act, the responsibility of government is reviewed. The guidelines defined in the Act may be used as an example to illustrate general political institutional relationships, related to transformation of research and development efforts into operational systems. Federal activities are within the following areas:

1. Policy Formulation. The interactions and direction of pollution controls must be articulated to the Nation so that government, industry, and individual citizens will support necessary actions
2. Research and Development. The development of new and improved techniques for pollution control requires government action not commonly associated with local/state government because of national needs and the cost of research
3. Demonstration. National needs and high costs almost dictate that the Federal Government support demonstration programs because new emerging technology and systems are both expensive and unpredictable
4. Technical Assistance. The provision of highly skilled technical expertise to assist local government and industry in dealing with problems
5. Planning Pollution Control Systems. Federal grants are provided to State governments to help them develop long-range plans for their States

6. Training. Pollution Control Acts provide the Federal Government with authority to train personnel in State and local government and private industry and to directly help universities establish college curricula to determine national manpower needs

7. State-of-the-Art Studies. Studies are made of existing technology to determine application and acceptability of technology im meeting objectives

8. Public Information.[76]

Examples of political institutional relationships between EPA, State and local governments are as follows:

1. EPA plays a coordinating role in a project called, "Mission 5000," which includes members from all levels of government and civic service, trade, health and conservation organizations.[77] The purpose of the project is to close dumps and develop systems which recycle wastes. In addition to technological and scientific R&D efforts, studies are being conducted by EPA on economic constraints which inhibit resource recovery.

2. EPA supported the Municipality of Metropolitan Seattle to build and operate advanced sewage facilities.[78] The system removes phosphates, has a computer-controlled storage subsystem, and removes sludge for landfill.

3. Demonstration grants have been supported in Baltimore, St. Louis, and San Diego for providing an approach to recovering the energy value of refuse.[79]

Regional offices of EPA assist the States in regulation and administer State and local assistance grants. Grants include: waste water treatment works construction grants, water pollution control comprehensive basis planning grants, air pollution control program grants, and solid waste planning grants.

The largest share of EPA's resources are spent for direct assistance to State and local governments. EPA's State and local assistance programs represented 85 percent of EPA's budget in 1972.[80] The programs have been decentralized and are administered by the Regional Office structure.

International

United Nations General Assembly Resolution 2997 established a governing council for environmental programs.[81] The EPA was designated as the United States information center in the global environment data distribution system established by the United Nations.[82]

EPA has a research commitment to the United States-Canada Great Lakes Water Quality Agreement of 1972.[83] The commitment involves a study concerning freshwater systems characterization and impact assessment.

CHAPTER IX

RESOURCE MANAGEMENT: MANPOWER

Long range "policy planning" for staffing EPA's scientific/technical personnel needs is contained within Pollution Control Acts passed by Congress. Provisions for a training program are in the Federal Water Pollution Control Act. Training grants have been given to provide university training for the purpose of employment in agencies or related air pollution control jobs. Traineeships since 1969 through fiscal year 1975 have supported 325 students at the bachelor's level, 1276 at the master's level, and 175 at the doctoral level.[84]

Another example of long-range planning is the New England Consortium on Environmental Protection.[85] It has been in existence since 1970 for education, training, and placement of individuals in Federal, State, and local air pollution control and environmental control agencies in the New England area. Fourteen New England universities are engaged in manpower development activities primarily under support of EPA's Office of Academic Training, Air Pollution Training Institute, Research Triangle Park, North Carolina.

Short range staffing of EPA's scientific/technical personnel has been accomplished by shifting staff and/or contracting out greater portions of work.[86] The staff available for research programs has continually diminished(see Table V), during the last several years. Personnel had to be drawn from the existing staff, when major dollar resources were provided to EPA for a multiagency program of energy development to parallel and lead

TABLE V

END-OF-YEAR EMPLOYMENT FOR RESEARCH AND DEVELOPMENT PERSONNEL BY MEDIA

Media	1974	1975	1976
Air	446	456	454
Water Quality	637	588	581
Solid Wastes	24	23	23
Pesticides	150	148	148
Radiation	82	72	57
Interdisciplinary	259	252	252
Energy	-	-	40
Toxic Substances	-	11	11
Noise	3	3	1
Program Management and Support	222	217	177
Reimbursable			85
Total	1898	1834	1904

SOURCE: Subcommittee on HUD-Independent Agencies, Hearings Before a Subcommittee of the Committee on Appropriations House of Representatives Ninety-Fourth Congress, First Session, part 6, Environmental Protection Agency Testimony of Members of Congress and Other Interested Individuals and Organizations (Washington, D.C.: Government Printing Office, 1975), pp. 46, 60-62.

ERDA's program of energy development. During the same time period, new problem areas have emerged that require personnel with different skills or increased effort.

In fiscal year 1976, a major re-examination of the mode of conducting operations has continued, after being initiated in fiscal year 1975.[87] This resulted in a shift of personnel from administrative duties to direct research functions; however, a skill mix problem remains. A review is being conducted on research needs in relation to the skill mix and staffing levels, given current and anticipated research requirements. The study will include a plan to alter the technical skill mix over a period of years. The present composition of personnel is shown in Table VI.

The Office of Planning and Management performs the agency-wide management functions involved in planning and implementing EPA programs. Within the preceding office is the Office of Education and Manpower Planning, which develops coordination of plans and evaluates the effectiveness of EPA's various manpower training programs. For fiscal year 1976, the Office of Education and Manpower Planning is staffed with four persons with a budget of $202,100.[88]

TABLE VI

NATIONAL ENVIRONMENTAL RESEARCH LABORATORIES PROFESSIONAL STAFF

Discipline	BS	BA	MS	MA	DVM	ScD	MD	PhD	Total
Biological and Agricultural Sciences	95	25	65	9	0	2	0	62	258
Chemistry	146	21	54	0	0	1	0	80	302
Engineering	90	1	125	0	0	3	0	34	253
Health Fields	4	0	20	0	13	1	35	19	92
Mathematical Sciences	16	6	18	0	0	1	0	5	46
Physical Sciences	20	5	36	1	0	0	0	15	77
Other	24	13	25	6	0	0	0	18	86
Total	395	71	343	16	13	8	35	233	1114

SOURCE: Environmental Protection Agency, National Environmental Research Centers, catalog number EP 1.2:N 21 c/3: Georgetown University Library-Government Documents Depository (Washington, D.C.: Environmental Protection Agency, 1973), pp. 6, 12, 20, 28.

SUMMARY

The Environmental Protection Agency has a unique mission, with objectives one must sympathize with because of its regulatory assignment. The Agency is caught in a crossfire between the ecology movement and the organizations which it regulates. Some groups feel regulations are too lenient, while others view regulations as overzealous and idealistic. The guidelines for regulation, contained in environmental statutes passed by Congress, lack a degree of consistency and are often based upon policy judgements that assume advances in control technology. Discretion is delegated to the Agency in providing factual analyses to promulgate regulations for execution of environmental law. Regulations may be on the frontiers of scientific knowledge and may lack a sufficient data base to make fully informed decisions. Concern for public health may overshadow risk/benefits judgements and discourage new technological innovations.

EPA has an indirect line of communication with the President via the Council on Environmental Quality. However, the Council has lost some of its influence with the present Administration because of the energy crisis.

EPA has shown some organizational anomalies because of its relatively recent formation from components of other agencies. It has been recommended that the laboratory structure be reduced to two systems--research and regulatory.

The outlays for Federal environmental research programs have been increasing as a percentage of the total R&D budget. However, research funds are not considered to be sufficient to meet all of the objectives of environmental mandates.

EPA is strongly dependent upon private enterprise and other Federal agencies to conduct its research programs. EPA is also dependent upon private enterprise for innovation in pollution control. The research program must meet control objectives by regulation, because research resources do not permit inhouse hardware development.

Within the personnel and financial constraints imposed, EPA is an innovative organization. The research results are being used to promote technology transfer and provide meaningful solutions to municipal and State governments.

The strongest benefit from EPA's research and development program is in technology assessment. EPA is in a unique position, compared to other agencies, to ensure technology assessment in all Federal R&D programs.

EPA has demonstrated a desire to promote a broad base of sociotechnical judgement in regulation formation. Regulation has been a difficult process because of the uncertainty of making technical decisons without a comprehensive data base to assess risks and benefits.

The future evolution of EPA is uncertain. EPA may become further divided into research and regulatory components. The research function of EPA is becoming diffuse with the growth of environmental research programs in other Federal agencies. Research growth is also constrained by budgetary allocations and the desire of Congress to avoid duplication of potential capabilities available in other Federal agencies. The research function may become more subservient to the regulatory function. Additional loss of research freedom will lessen the effectiveness of technology transfer by EPA's Office of Research and Development.

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AN OVERVIEW OF SCIENCE POLICY
AT THE
FOOD AND DRUG ADMINISTRATION

by

Susan J. Appleman

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INTRODUCTION

The modern Food and Drug Administration administers a broad Congressional mandate intended to provide effective consumer protection in the areas of food and drugs. In particular, the agency's mission is to ensure that food is safe, pure, and wholesome; human and animal drugs, biological products, and therapeutic devices are safe and effective; and radiological products and use procedures do not result in unnecessary exposure to radiation.[1]

To accomplish its mission, the FDA administers a variety of programs. The agency sets food and product standards; evaluates the safety and efficacy of new drugs before they are marketed; and conducts and sponsors research studies to detect health hazards and violations of laws or regulations. The agency informs business firms and consumers about FDA-related topics and also works with state and local agencies to develop programs that will supplement or complement those of FDA. In addition, the FDA maintains surveillance over foods, drugs, and electronic products to ensure that they are safe, effective, and properly labeled; and takes legal action where necessary to remove violative products from the marketplace and to prosecute firms or individuals that violate the law.[2]

Although its mission is primarily regulatory, the programs of the Food and Drug Administration regarding the safety of food and drugs must ultimately depend upon informed scientific judgment. Thus, the success of FDA in providing consumer portection hinges largely upon both the scientific data available (generated within and outside the agency) and the science policy of the agency that merges that data and subsequent subjective judgments for potent regulatory decisions. The purpose of this paper is to give an overview of science policy at the Food and Drug Administration, and to examine the impact of this policy on the regulatory mission of the agency.

The study was conducted by means of a literature search of agency publications, Congressional hearings, and secondary materials; and supplemented by personal interviews with members of the FDA staff. The scope of the study is limited because the author was not close to the day-to-day science policymaking at the agency. A close look of this type through further research is needed to compare and contrast informal, operating procedures and resultant decisions with written guidelines and testimony. However, this paper serves as a first step in assessing the form and function of science policy at the Food and Drug Administration.

Since the functions and programs of the agency are directed to support the regulatory mission, the basic elements of this function will be described in the first chapter. The following several chapters will examine specific aspects of organisation and management at the FDA, emphasizing their relationship to the implicit or explicit science policy of the agency. Finally, the large of question of decision-making in the area of science policy and its impact on the agency mission will be addressed.

CHAPTER I

THE REGULATORY PROCESS AT THE FOOD AND DRUG ADMINISTRATION

Diverse agencies within the Federal government have regulatory responsibility. The Food and Drug Administration administers laws and regulations promulgating an essential public good: the safety and purity of foods and drugs. The regulatory decisions of the agency have far-reaching impact, since they affect not only the manufacturers of the products being regulated but also every person in the nation who consumes these products.

Clearly, scientific evidence underpins the regulatory decision-making of the Food and Drug Administration. The agency seeks to meld scientific fact with existing laws to formulate regulations that result in effective consumer protection. The first step, then, in the examination of science policy at the Food and Drug Administration should involve a look at the regulatory process of the agency and determine where science and science policy play a part.

The Congressional mandate for the FDA is found in several laws administered by the agency. Its present organization reflects its regulatory authority and responsibilities. The general process of regulation and enforcement encompass hard scientific data, subjective judgments on acceptable benefits and risks, and various avenues to assure that manufacturers comply with regulations once they are established. Science in its present level of sophistication cannot provide all the answers needed by the regulator, however, so that the process of regulation is difficult, controversial, and complex.

The Laws and Regulations

Shocking disclosures of insanitary conditions at meat packing plants, the use of poisonous preservatives and dyes in foods, and cure-all claims for worthless and dangerous patent medicines spurred the enactment by Congress of the Food and Drugs Act of 1906. This first law to demand protection of the public from unsafe food and drugs prohibited the use in food of "any added poisonous or other added deleterious ingredient which may render such article injurious to health" and similarly prohibited the use in drugs of any "ingredient deleterious or detrimental to health."[1]

The Act of 1906 served as the basic fabric of consumer protection for 32 years, until the passage of the Federal Food, Drug, and Cosmetic Act of 1938. This Act reiterated and extended the 1906 law to form the legal basis for the primary responsibility of the modern Food and Drug Administration.

The Food, Drug, and Cosmetic Act is intended to assure the consumer that: foods are pure and wholesome, safe to eat, and produced under sanitary conditions; drugs and medical devices are safe and effective for their intended uses (including drugs used in medicated feeds for animals); cosmetics are safe and properly labeled; and packaging and labeling of these products is truthful and informative. Of the 11 subsequent amendments to the 1938 Act, several are particularly prominent. The Food Additives Amendment of 1958 prohibits the introduction of new food additives until the manufacturer can prove their safety. The Color Additive Amendments of 1960 gave the FDA authority to control the conditions for safe use of a color additive, including the amount of color used in a product. The Kefauver-Harris Drug Amendments of 1962, intended to assure a greater degree of drug safety, required that drug manufacturers also prove the effectiveness of products before marketing them. The 1962 amendments also gave FDA authority to regulate prescription drug advertising.[2]

In addition to the Food, Drug, and Cosmetic Act of 1938, the laws given below complete the bases for the overwhelming majority of FDA activities. The Fair Packaging and Labeling Act of 1966 requires truthful and accurate packaging and labeling; FDA enforces provisions affecting foods, drugs, and cosmetics, and medical devices. The Radiation Control for Health and Safety Act of 1968 protects the public from unnecessary exposure to radiation from medical x-rays and electronic products. The Public Health Service Act of 1944 regulates the quality of biologic drugs. Under another section of the law, FDA assures the safety of pasteurized milk and shellfish, and the sanitation of food services and the food, water, and sanitary facilities for travelers on trains, planes and buses. The Tea Importation Act of 1897 is designed to insure the quality of imported tea.[3]

Title 21, Code of Federal Regulations, consists of seven volumes containing all regulations issued under the Food, Drug, and Cosmetic Act and the other statutes administered by the Food and Drug Administration. These volumes are updated each year to incorporate all regulations issued during the preceeding twelve month period. All the regulations for the current year are published in the Federal Register, an official publication which carries full texts of Presidential Proclamations and Executive Orders and the regulations of other agencies. The seven volumes of Title 21 consist of:

Parts 1 through 9—General regulations, color regulations, and Fair Packaging and Labeling regulations.
Parts 10 through 199—Food standards, Nutritional Quality Guidelines, and food additive regulations.
Parts 200 through 299—General drugs, labeling, prescription drugs, etc.
Parts 300 through 499—Drugs for human use, new drugs, New Drug Applications.
Parts 500 through 599—Animal drugs, feed, and related products.
Parts 600 through 1299—Cosmetic regulations; also regulations covering hazardous substances, the Federal Import Milk Act, Tea Import Act, biologics and radiological health.

Parts 1300 to End—Regulations issued by the Drug Enforcement Administration, Department of Justice, for the control of narcotics and dangerous drugs.[4]

Organization for Regulation

The Food and Drug Administration headquarters staff consists of the Office of the Commissioner and seven bureaus: Biologics, Drugs, Foods, Medical Devices and Diagnostic Products, Radiological Health, and the Executive Director of Regional Operations (see Figure 1). Ten field offices span the United States and carry out all the field activities necessary for the enforcement of the laws under the jurisdiction of the FDA. The locations of the regions are shown in the map in Figure 2.[5] (Additional organization charts are given in Appendix I.)

Each bureau has a particular responsibility within the broad mission of the FDA. The Bureau of Biologics conducts regulatory compliance programs to insure the safety, purity, potency, and efficacy of biological products which include antitoxins, blood and blood derivatives, bacterial vaccines, toxoids and toxins, diagnostic substances, and other biologic products. The Bureau of Drugs primary objective is to protect the consumer by assuring that drugs and devices on the market are safe and effective. The Bureau of Foods conducts research and develops standards and policy on the composition, quality, nutrition, and safety of foods, food additives, colors, cosmetics, and other potentially harmful industrial chemicals.

The Bureau of Medical Devices and Diagnostic Products develops FDA policy regarding the safety, efficacy and labeling of medical devices and in-vitro diagnostic products. The Bureau of Radiological Health carries out programs designed to reduce the exposure of man to hazardous radiation. The Bureau of Veterinary Medicine develops medical policy for the agency with respect to the safety and efficacy of veterinary preparations and devices. The Executive

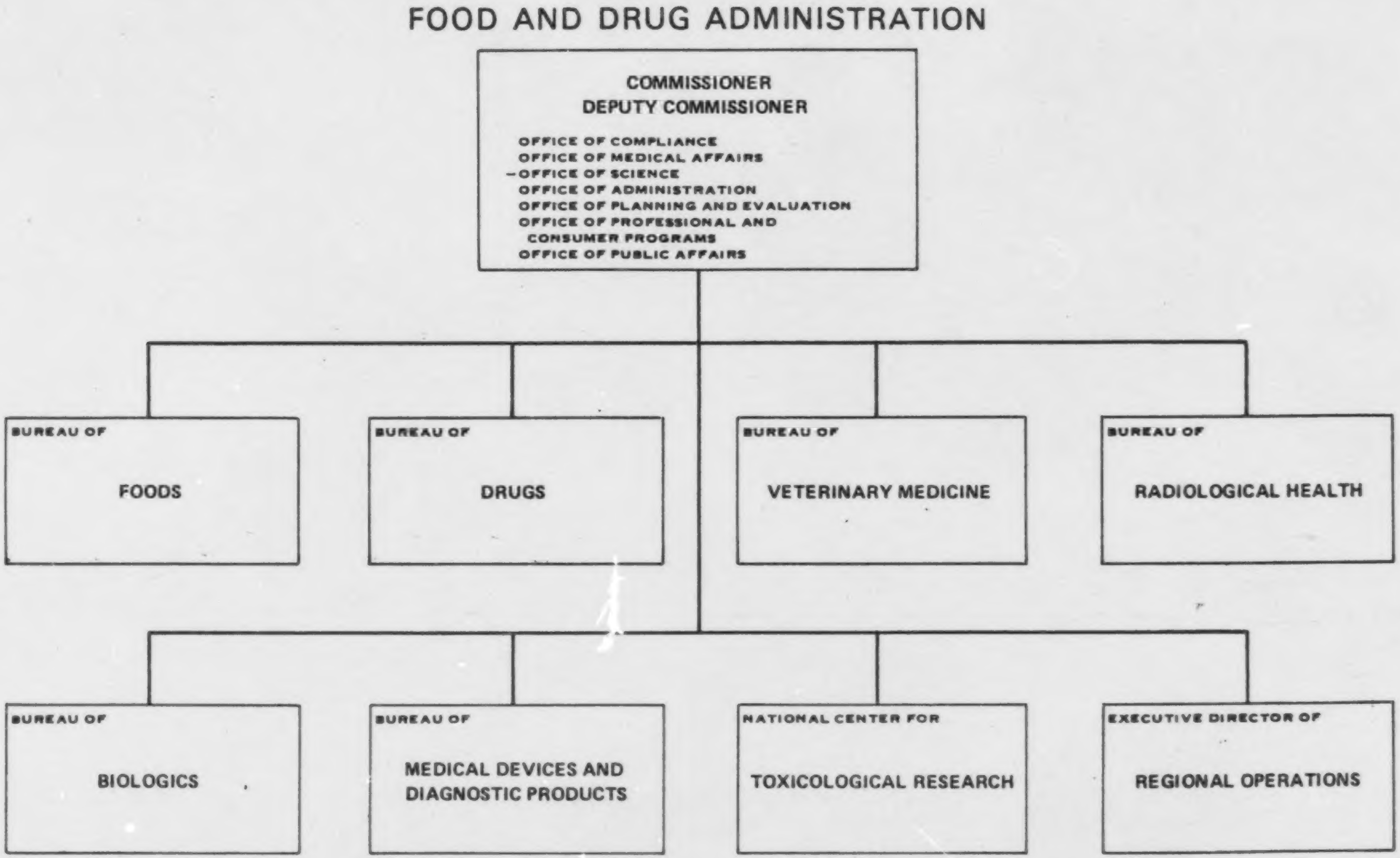
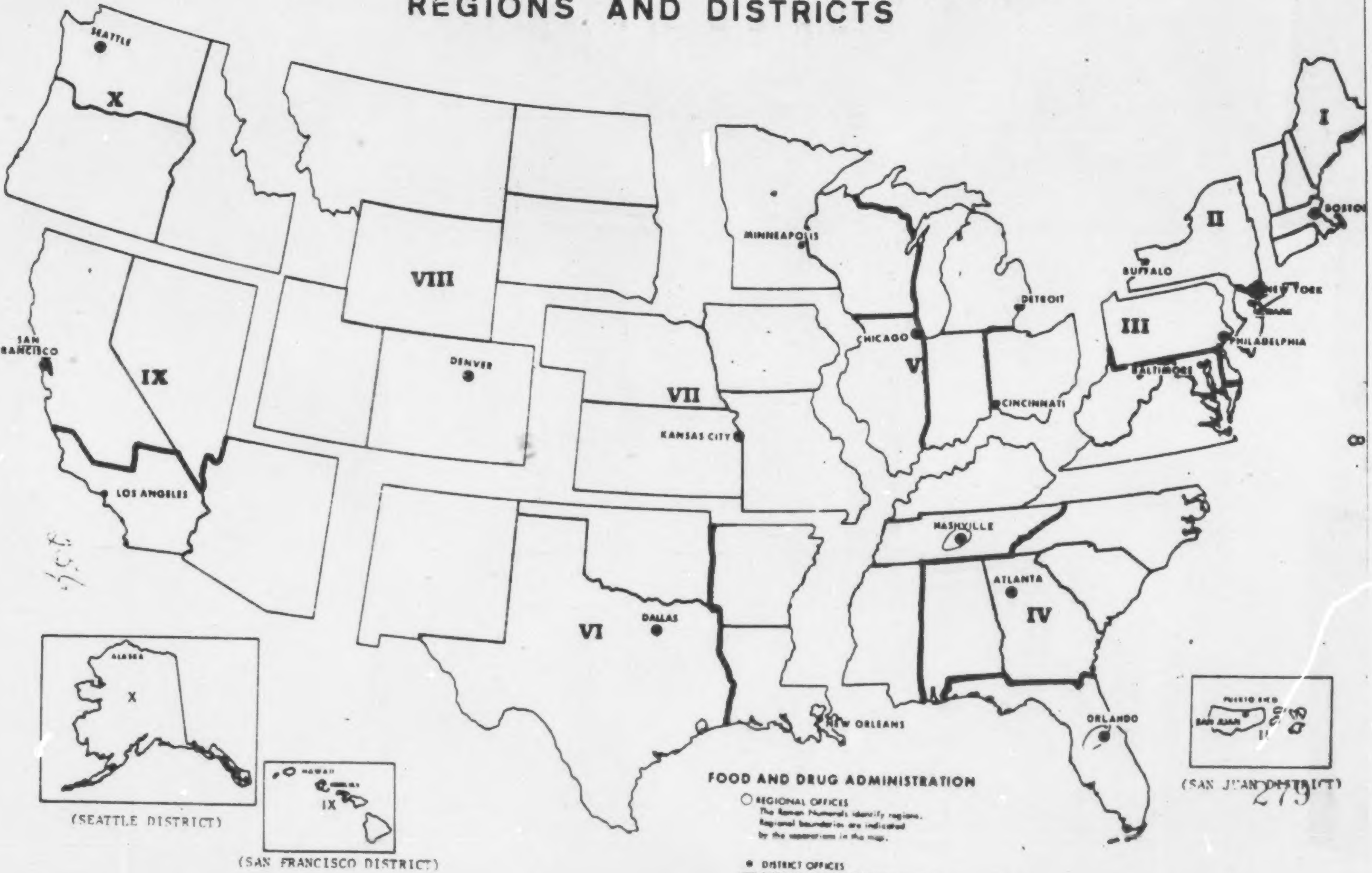

FOOD AND DRUG ADMINISTRATION
COMMISSIONER
DEPUTY COMMISSIONER
OFFICE OF COMPLIANCE
OFFICE OF MEDICAL AFFAIRS
OFFICE OF SCIENCE
OFFICE OF ADMINISTRATION
OFFICE OF PLANNING AND EVALUATION
OFFICE OF PROFESSIONAL AND CONSUMER PROGRAMS
OFFICE OF PUBLIC AFFAIRS
BUREAU OF FOODS
BUREAU OF DRUGS
BUREAU OF VETERINARY MEDICINE
BUREAU OF RADIOLOGICAL HEALTH
BUREAU OF BIOLOGICS
BUREAU OF MEDICAL DEVICES AND DIAGNOSTIC PRODUCTS
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH
EXECUTIVE DIRECTOR OF REGIONAL OPERATIONS

Figure 1

FDA Headquarters Organization

Figure 2

THE FOOD AND DRUG ADMINISTRATION REGIONS AND DISTRICTS


SEATTLE
X
VIII
MINNEAPOLIS
II
I
BOSTON
BUFFALO
NEW YORK
NEWARK
DETROIT
CHICAGO
III
PHILADELPHIA
BALTIMORE
SAN FRANCISCO
IX
DENVER
VII
V
CINCINNATI
KANSAS CITY
LOS ANGELES
NASHVILLE
ATLANTA
IV
DALLAS
VI
NEW ORLEANS
ORLANDO
ALASKA
X
(SEATTLE DISTRICT)
HAWAII
IX
(SAN FRANCISCO DISTRICT)
PUERTO RICO
SAN JUAN
II
(SAN JUAN DISTRICT)
FOOD AND DRUG ADMINISTRATION
○ REGIONAL OFFICES
The Roman Numerals identify regions.
Regional boundaries are indicated
by the separations in the map.
● DISTRICT OFFICES
▬ DISTRICT BOUNDARIES (within regions)

Director of Regional Operations executes direct line authority over all FDA field operation. This office develops, issues, approves, or clears proposals and insturctions affecting the field activities, and provides direction to Regional Food and Drugs Directors in the execution of the policies and operational guidelines which form the framework for management of FDA field activities.[6]

The Process of Regulation and Its Enforcement

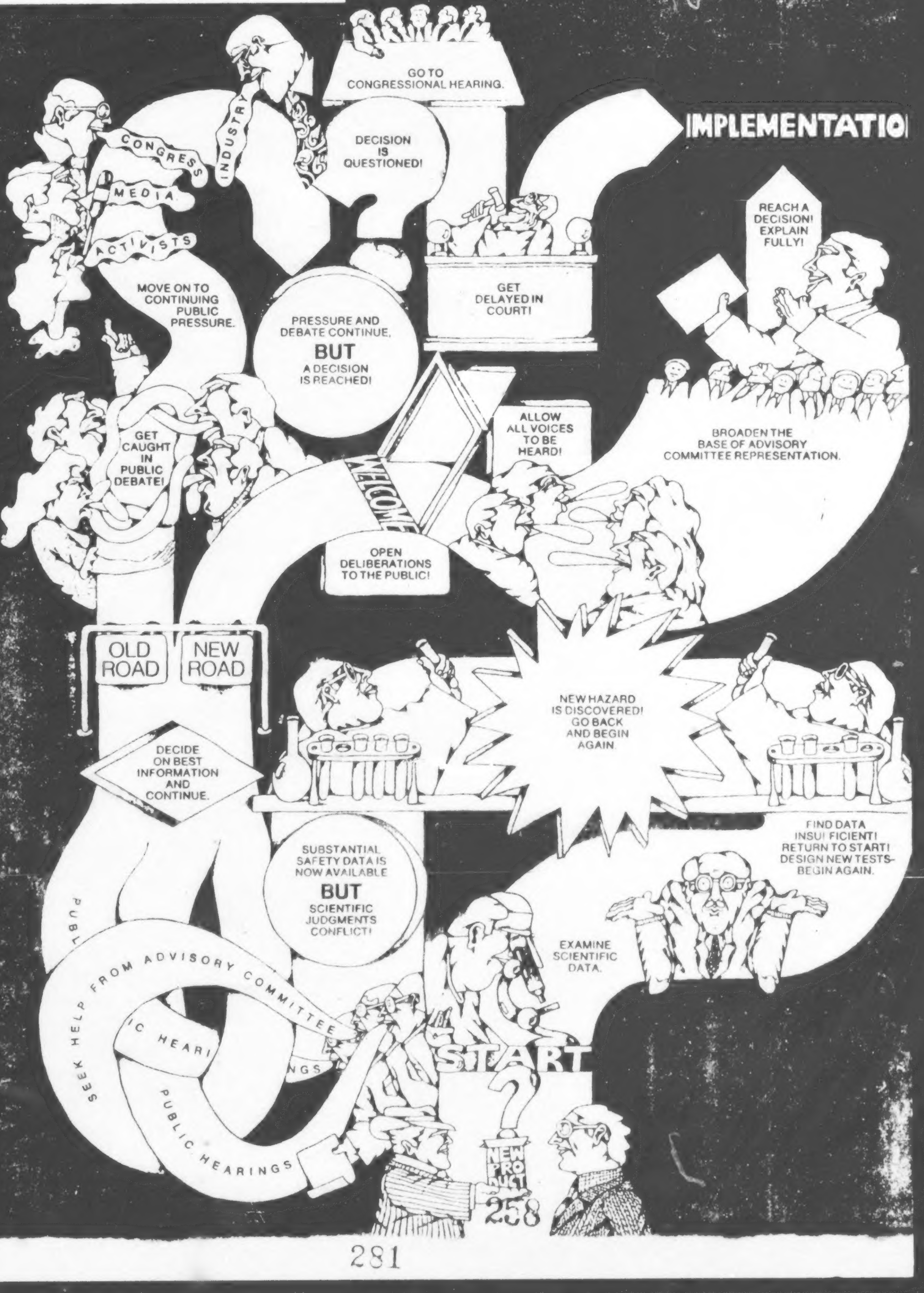
The regulatory process at the Food and Drug Administration has two main aspects: the formulation of new and review of existing regulations; and the enforcement of extant regulations as cited in Title 21. Scientific input provides the foundation in forming and reviewing regulations, while the legal aspects of safety and efficacy predominate the enforcement role.

In its most general form, the decision-making process can be represented by the flow chart in Figure 3. The starting point "new product" can depict a variety of things: a new drug application being submitted for approval; an item on the foods GRAS (Generally Recognized as Safe) list under review; or proposed production methods for influenza vaccines. The bureau responsible for that "new product" reviews scientific data on its safety and effects in man in order to make a determination of the benefits and risks to be expected. This data can come in large part from a manufacturer requesting approval, as in a new drug application, and also from other scientific experts and the literature. In some cases, the FDA will conduct its own experiments to gather pertinent data. The agency broadens its expertise by consulting independent technical advisory committees, consisting of scientific experts, to provide advice on major issues.[8]

Proposed regulations issued by FDA are first published in the Federal Register for public comment. Comments are solicited from the general public, academia, consumer groups, industry, and any other interested parties. All

Figure 3

The general decision-making process


START
NEW PRODUCT
EXAMINE SCIENTIFIC DATA.
FIND DATA INSUFFICIENT! RETURN TO START! DESIGN NEW TESTS- BEGIN AGAIN.
NEW HAZARD IS DISCOVERED! GO BACK AND BEGIN AGAIN.
SUBSTANTIAL SAFETY DATA IS NOW AVAILABLE BUT SCIENTIFIC JUDGMENTS CONFLICT!
SEEK HELP FROM ADVISORY COMMITTEE
PUBLIC HEARINGS
PUBLIC HEARINGS
PUBLIC HEARINGS
DECIDE ON BEST INFORMATION AND CONTINUE.
OLD ROAD
NEW ROAD
OPEN DELIBERATIONS TO THE PUBLIC!
WELCOME
ALLOW ALL VOICES TO BE HEARD!
BROADEN THE BASE OF ADVISORY COMMITTEE REPRESENTATION.
REACH A DECISION! EXPLAIN FULLY!
IMPLEMENTATIO
GET CAUGHT IN PUBLIC DEBATE!
PRESSURE AND DEBATE CONTINUE, BUT A DECISION IS REACHED!
MOVE ON TO CONTINUING PUBLIC PRESSURE.
ACTIVISTS
MEDIA
CONGRESS
INDUSTRY
DECISION IS QUESTIONED!
GO TO CONGRESSIONAL HEARING.
GET DELAYED IN COURT!
258

responses are filed and available to public view in the Office of the Hearing Clerk. Public hearings encourage further participation. The final form of the regulation is then implemented, and the rationale for the decision and underlying documentation are published.[9]

Once the Agency has acted, there are various forums available for continued public debate. A major safety decision may result in a Congressional hearing to investigate the availability and use of facts and the weighing of viewpoints that took place in the regulatory decision. For those in industry or consumer groups who disagree with agency decisions, the courts offer a remedy for grievances. In addition, a major issue is likely to prompt public debate for months or years after the actual decision. Finally, new scientific evidence may take the issue back to the "new product" stage, where a new decision-making process begins.[10]

The Food and Drug Administration has several avenues for the enforcement of regulations once they have been established. Decisions by the U.S. Supreme Court in 1973 emphasized the principle that the agency has "primary jurisdiction" to enforce the Federal Food, Drug, and Cosmetic Act and that its decisions have "administrative finality." The result of these decisions has been a move away from a dependence on the courts to handle the enforcement of the law, and an emphasis on the fullest use by the FDA of its administrative powers, especially for minor violations.[11]

These decisions prompted the use of a new law enforcement mechanism—the "Regulatory Letter." These letters are formal notices to a specific person or firm, charging specific violations of the law, setting a date for corrective action, and advising the parties that a court proceeding will be begun if the violations are not corrected.[12]

If a case warrants legal action, several avenues are available: (1) seizure of products on the market in which misbrandings or adulteration have been confirmed; (2) an injunction to halt a violative process; or (3) criminal proceedings against a company and its officers because of continued and aggravated violations. Many violations are minor in nature, and can be handled without court action; that is, with the regulatory letter.[13]

If a product is found to violate the law, a product recall by the manufacturer is a common form of corrective action. Once a health hazard and its extent are determined, a recall strategy is developed to include the depth of recall, the necessity of publicity, and checks for effectiveness. Classes of recalls have been set to reflect actions needed by the FDA and the regulated firm, depending on the potential hazard to the consumer.[14]

There are about 1000 consumer safety officers assigned to FDA posts across the United States who inspect the plants where products regulated by the FDA are processed, packed, or stored.[15] If the safety officers discover a violation, compliance officers at the field level work with the responsible bureau and the Office of General Counsel to determine appropriate actions to insure compliance with the law.[16] The Office of Compliance, a staff role in the Office of the Commissioner, advises on compliance matters, with emphasis on overall policy and direction. This office evaluates and coordinates the agency's overall compliance efforts to insure an optimum use of resources, and serves as the focal point to coordinate FDA-industry relations to maximize compliance.[17]

Safety Regulation in the Real World

At a first observation, it would seem that the regulation of the safety of food and drugs would be a simple task. Scientific fact would be compared with explicit statutory requirements to produce clear and widely-accepted regulatory results.

However, as Peter Barton Hutt, former FDA General Counsel, points out, safety regulation in the real world is not so neat and clear-cut. On the one hand, scientific uncertainty on many matters precludes wholly objective standards, and, on the other hand, the Congressional mandate to the FDA is couched in broad guidelines on food and drug safety, not narrow and specific rules.[18]

In this environment, then, Hutt outlines five basic obstacles to the decision-making process on safety issues:

> (1) The scientific data base is seldom adequate to make a definitive safety judgment on any food or drug.
> (2) Even when substantial safety data are available on a particular substance, there is seldom scientific agreement on the meaning or significance of that information.
> (3) There appears to be no public or scientific consensus today on the risk or uncertainty acceptable to justify the marketing of any substance as a food or drug.
> (4) There is enormous and continuing public pressure for FDA to resolve safety issues promptly and decisively.
> (5) Regardless of the outcome of the decision, those who disagree with it will continue to pursue the matter through all available channels, while those who agree with it will inevitably remain silent, preparing themselves for the next issue.[19]

It is clear that the agency operates in a difficult environment, with pressures from many directions. The Food and Drug Administration is being called upon to make definitive regulatory decisions based on sometimes inadequate scientific information and conflicting scientific judgments. Until science can provide an equation that relates food and drug input and interactions to positive human effects, the FDA will continue to depend on subjective judgments to supplement hard scientific fact. Since the formulation of such an equation is unlikely for the near future, it seems the best course for the FDA is one which encourages the widest possible participation by all interested parties in that subjective portion of the decision-making process.

Science does underpin all regulatory decision-making by the agency, but is not the only part of the process. The policy of the agency with regard to science must place scientific fact and judgment into proper perspective—

not over-relying on science for answers it cannot provide, but also not ignoring science in the face of administrative or political pressures.

CHAPTER II

FISCAL CONSIDERATIONS

The Food and Drug Administration employs 6303 persons and has a budget of $208,608,000 to carry out the agency's regulatory mission. These dollars fund programs ranging from field inspections of food manufacturing plants to research on DES at the National Center for Toxicological Research.

Table 1 illustrates the breakdown, by major component, of the Fiscal Year 1976 budget. The allocation of funds at the Bureau level includes all programs related to that Bureau's functional responsibility; for example, it includes field operations, administrative expenses for the Bureau, and research in its area of concern. An interesting note is that the Bureau of Foods and the Bureau of Drugs constitute 70 percent of the agency's total budget. Program Management, which is comprised of the Office of the Commissioner, Associate and Assistant Commissioners, and general management personnel responsible for the overall executive direction and servicing of agency programs, commands 12 percent of the budget.[1]

Table 2 presents the line item breakdown of the 1976 funds expended, as presented in the 1977 budget request to Congress. This presentation emphasizes the programmatic approach to the budgetary process. The Fiscal Year 1977 budget request asks for an increase of 71 persons to 6,374 and an accompanying increase of funds to $223,105,000, up $14,497,000 or 6.9 percent.[2]

It should be noted that research and development costs are not included as a line item in the budget, but rather are incorporated into the Bureau

TABLE 1[3]

ALLOCATION OF FDA FUNDS—FISCAL YEAR 1976

	Positions	Dollars	Percent of total dollars
Foods	2232	66,056,000	31.67
Cosmetics	81	2,581,000	1.24
Drugs	2573	76,208,000	36.53
Devices	281	8,222,000	3.94
Radiological Products	466	17,688,000	8.48
National Center for Toxicological Research	221	12,065,000	5.78
Program Management	449	25,788,000	12.36
Totals	6303	208,608,000	100.00

Table 2^4

DISTRIBUTION OF FDA RESOURCES BY PROJECT AREA

	Positions	Dollars $000	Percent of Total Positions	$
FOODS				
Food Safety				
Food Sanitation Control	1,136	31,971	18.1	15.4
Food Additives	148	4,959	2.3	2.4
Chemical Contaminants	349	9,451	5.5	4.5
Interstate Travel	125	4,120	2.0	2.0
Mycotoxins and Other Natural Poisons	108	3,740	1.7	1.8
Nutrition	106	3,632	1.7	1.7
Shellfish Safety	84	2,794	1.3	1.3
Food Service	81	2,745	1.3	1.3
Total Food Safety	2,137	63,412	33.9	30.4
Food Economics	95	2,644	1.5	1.3
Cosmetics	81	2,581	1.3	1.2
TOTAL FOODS	2,313	68,637	36.7	32.9
DRUGS AND DEVICES				
Human Drugs				
Prescription Drug Labeling and Compendium	3	278	0.1	0.1
Clinical Investigation Evaluation	42	1,053	0.7	0.5
Biopharmaceutics	52	2,080	0.8	1.0
Drug Abuse Treatment Monitoring	65	1,751	1.0	0.8
Drug Quality Assurance	862	21,229	13.7	10.2
New Drug Evaluation	450	12,893	7.1	6.2
Drug Efficacy Study Implementation	141	3,561	2.2	1.7
Drug Listing	68	2,108	1.1	1.0
Drug Experience & Trends Analysis	48	2,020	0.8	1.0
OTC Drug Evaluation	58	1,701	0.9	0.8
Poison Control	19	749	0.3	0.4
Prescription Drug Advertising	15	529	0.2	0.3
Total Human Drugs	1,823	49,952	28.9	24.0
Veterinary Drugs				
Animal Feed Safety	97	3,687	1.5	1.8
Drug Residues	48	1,715	0.8	0.8
Animal Drug Safety	188	6,079	3.0	2.9
Antibiotics in Animal Feeds	26	1,008	0.4	0.5
Total Veterinary Drugs	359	12,489	5.7	6.0
Medical Devices	281	8,222	4.5	3.9

TABLE 2—Continued

		Dollars	Percent of Total	
	Positions	$000	Positions	$
Biologics				
Blood and Blood Products	749	5,523	2.8	2.7
Viral and Rickettsial Products	110	4,464	1.8	2.1
Bacterial and Allergenic Products	87	3,051	1.4	1.5
Safety, Efficacy, and Labeling Review	15	729	0.2	0.3
Total Biologics	391	13,767	6.2	6.6
TOTAL DRUGS AND DEVICES	2,854	84,430	45.3	40.5
RADIOLOGICAL PRODUCTS				
Ionizing Radiation—Products and Devices	187	6,963	3.0	3.3
Ionizing Radiation—Use Control	130	4,664	2.1	2.2
Light and Sonic Radiation	82	3,569	1.3	1.7
RF Microwave	67	2,492	1.0	1.2
TOTAL RADIOLOGICAL PRODUCTS	466	17,688	7.4	8.4
NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH	221	12,065	3.5	5.8
PROGRAM MANAGEMENT	449	25,788	7.1	12.4
TOTAL, FOOD AND DRUG ADMINISTRATION	6,303	208,608	100.0	100.0

requests. Table 3 gives the dollars allocated to research at the agency. The total is approximately 20 percent of the agency's total budget in Fiscal Year 1976.

With its resources, FDA regulates industries whose products are estimated at $300 to 400 billion a year.[5] In terms of cost to the consumer, the budget comes to about a dollar a year per person in the United States.[6]

For comparison, the Food and Drug Administration's budget is 0.22 percent of the Department of Defense budget of $91.2 billion.[7] Looking at the research component of the funds, FDA research in 1976 is 0.49 percent of what was allocated to Department of Defense research and development in Fiscal Year 1974, 1.79 percent of the total Department of Health, Education, and Welfare R&D prescribed for 1974, and 2.37 percent of the National Institutes of Health budget for that year.[8]

So, not only is the FDA budget small in comparison to other agencies, and within DHEW, the funds it allocates to research are small when compared to other agency support of R&D nationwide. This allocation of research funds should not be surprising, though, since the support of research and development is not a major part of the mission of the agency. Furthermore, the research that is supported by FDA is in large part directly related to the regulatory mission (e.g., analysis of products to determine possible adulteraion, development of analytic techniques for residue detection, etc.).[9]

TABLE 3[9]

FDA RESEARCH FUNDS—FISCAL YEAR 1976

	Dollars
Foods	10,445,000
Drugs and Devices[a]	13,107,000
Radiological Products	5,521,000
National Center for Toxicological Research[b]	12,065,000
Total	41,138,000[c]

[a] Of this total, approximately 40% goes to Drugs, 40% to Biologics, 15% to Veterinary Medicine, and 5% to Medical Devices.

[b] The total budget for NCTR is given as a research budget.

[c] Of this total for the agency, $10,800,000 is committed to contractural arrangements.

CHAPTER III

FDA MANPOWER MANAGEMENT

Any discussion of science policy at the Food and Drug Administration must include a look at the scientist at FDA—the type of science he performs, how he is managed, and how his role is perceived.

The FDA currently employs 6303 persons, of whom 2500 are field employees. The majority of the professionals in the agency have scientific backgrounds; they are supported by a small administrative staff. Among those scientists currently performing research and analysis (i.e., excluding management personnel), almost half are chemists; other large groups include biological technicians, microbiologists, biologists, veterinarians, and doctors.[1]

To enforce the Food, Drug, and Cosmetic Act and the other legislation under the agency's purview, two general types of scientific activity are performed. At the field level, analysts do routine laboratory work to check if inspected products meet current regulatory standards. At the Washington, D.C. labs, the focus is on analytic methodology pertinent to the agency's mission. This includes both the review of other scientists' work in support of a new drug or food additive, for example, and also research on improved methodologies themselves.[2] Both field and headquarters activities are clearly needed; laws to insure the potency of drugs and purity of foods would be unenforceable without the proper analytic methods to determine what a standard should be and if a product meets the standard. In addition, more basic research on the long term effects of chemicals on man are being studied at the

National Center for Toxicological Research. The kind of science being done at this laboratory is discussed in detail in Chapter 6, "The Issue of Technology Assessment."

The Field Organization

The scientific field organization consists primarily of consumer safety inspectors (about 1200 out of the 2500), analysts (mainly chemists and microbiologists), and compliance officers (often former inspectors or analysts). Supervisory personnel are, in general, former investigators or analysts.[3] FDA policy supporting the appointment of the supervisors seems consistent with the general view that scientists are best equipped to supervise other scientists.

Training at the field level emphasizes skills for the professionals that will enhance their ability to perform the regulatory function. Safety inspectors take in-house or university courses that describe, for example, drug manufacturing practices or food sanitation processes. Chemists study techniques in the analytical chemistry of foods, drugs, additives, or pesticides; microbiologists likewise learn techniques for analysis on products and raw materials to detect microorganisms. Compliance officers study pertinent laws. In addition, an upward mobility program is providing funds to assist about 100 low-grade clerical personnel in taking courses to help them reach professional status.[4]

The professional positions at the field level (as well as in headquarters) are part of the Federal Civil Service system. Chemists, microbiologists, and other scientists enter at the GS-5 level with appropriate college credentials in their fields; consumer safety officers must have a bachelor's degree with at least 30 semester hours of science. Entrance at the GS-7 level or higher levels depends on criteria for outstanding scholastic performance, higher degrees, or previous work experience.[5]

Personnel can be rotated between different positions (analyst to compliance officer, for example) in different training details. Professionals are transferred between field offices when special expertise is needed; this does not happen frequently, however.[6]

According to Richard Baldwin, in the Office of Training and Education under the Executive Director of Regional Operations, in-grade step increases and cash awards can be earned by scientists whose quantity of work exceeds a certain expected level. The supervisor is responsible for recommending his people for increases or awards.[7]

The professionals at the field level can properly be called scientists, since they do employ the methods of science to analyze products regulated by the FDA. However, the type of science done in the laboratories cannot be called research and development in food and drugs. In the first place, FDA does not have as part of its mission R&D at the frontiers of knowledge in food and drug science. In addition, R&D in the analytic methods needed by FDA to enforce the Food, Drug, and Cosmetic Act is centered at the headquarters laboratories. Scientists at the National Center for Toxicological Research are closer to the frontiers of understanding the effects of chemicals on humans. The implication is that the majority of the scientists in the field are really technicians (analysts), and that their success or failure depends not on their innovative abilities, but on their knowledge and ability to apply the most current testing methodology. A training program that encourages the professionals to stay current in the modern techniques of analysis is imperative. In addition, it is evident that the scientists will probably remain technicians, as they behave in a manner consistent with the measure of their performance——quantity of work done.

Mr. Baldwin, in commenting on current personnel practices at field laboratories, also implied that the presence of the recession is making efforts to hire and hold good scientists less necessary than when many positions for scientists are generally available. At one time in the agency, chemists were given cash bonuses to attract them to FDA (when the demand for chemists in the economy as a whole exceeded the supply). Now, many positions on the Civil Service Register are backlogged and some have been closed.[8] The lack of "normal" attrition may tend to discourage FDA administrators' planning policy for hiring and holding good scientists. However, continual review of current personnel practices should be conducted, with concurrent studies of the factors that attract scientists to FDA and the factors that motivate them to stay. This is even more important in light of the value of experience that is central to headquarter and field laboratory success. A high rate of attrition could severly hamper the labs' capacity to generate the information needed to formulate and enforce FDA regulations.

Headquarter's Manpower and Management

George Schwartzman, Assistant to the Associate Director for Planning and Program Coordination, Pharmaceutical Research and Testing, Bureau of Drugs, maintains that the main purpose of headquarters research and development (as well as all science performed in the agency) should be focused towards tools needed to accomplish enforcement of the Food, Drug, and Cosmetic Act. Scientists at headquarters labs not only evaluate food and drug companies' methodologies cited to prove safety and efficacy and make judgments on the adequacy of the data and conclusions drawn from them, they also test and develop analytic methodology related to the agency's mission.[9]

As for the scientists in the field, the Food and Drug Administration will pay for university courses that will enhance the professionals' on-the-job ability. Seminars and on-the-job training further supplement their abilities.[10]

Several formal programs in management training are available to individuals at several levels in the agency. The outlook of the agency appears to be one of promotion from within, encouraging lower-level professionals to become as knowledgeable as possible so that they can become effective leaders in the future.

The Management Intern Program is a two-year program, open to employees at the GS-7 or GS-9 levels. Rotational on-the-job training assignments designed to develop administrative and managerial competence are supplemented with a core curriculum of courses conducted by the U.S. Civil Service Commission and local universities. Rotational assignments range from Bureau level experience to field work, and course work includes management theory, food and drug law, budget and contract issues, and others Currently, six persons are involved in this management program.[11]

The Mid-Level Career Development Program is of 12 to 18 months in duration, and accomodates about 18 Associates. This program enables the person to become more familiar with overall agency policy, organizational goals, and program priorities. To enhance the professional's leadership and managerial capabilities, three separate career development programs are used: the task force, special training, and exchange assignments. The task force is composed of four to six Mid-Level Associates who research and solve current significant administrative and program problems at FDA. Specially created "training positions" at the headquarters and field level test the Associates creativity and initiative, while exchange assignments further enhance their skill development. The Mid-Level Program is open to levels GS-11, GS-12, and GS-13.[12]

Finally, the Executive Fellows Program encompasses the highest level management training program. Open to professionals at the GS-14 and GS-15 levels, this program is designed to develop qualified prrsons with diversified FDA work experience, a sound understanding of agency goals and objectives, and a good grasp of contemporary management theory and practice. Major elements of the Fellow's "Developmental Plan" include planned work assignments, formal training opportunities, and special projects, such as work on advisory committees or task forces. The twelve-month program is clearly designed to train professionals for possible vacancies in the agency's highest level management positions.[13]

These three programs represent a commendable effort by the Food and Drug Administration to prepare scientists to accept management responsibility at all levels of the agency. Not only are the most current management theories and practices studied by the professionals, but also a systems approach to agency management is being encouraged. Scientists in the programs focus on the workings of the entire FDA and how it interfaces with the rest of its environment. This attitude facilitates a mutual understanding among the FDA, industry, Congress, and the consumer, as managers are encouraged to look at the agency and their management responsibilities as part of a larger system. This is essential in the formulation and enforcement of meaningful regulation.

An Outsider's View of the Professionals of FDA

James S. Turner, founder and co-director of Consumer Action for Improved Food and Drugs, as project director of a Nader Report on the Food and Drug Administration, discussed the role and position of FDA scientists in a chapter in the report titled "Misused Professionals." According to the Study Group, the historically weak scientific position of the agency had not improved much by 1970. The "familiar" FDA policy remained a subordination of science to administrative decisions and needs. The resulting environment discouraged creativity, fostered self-censorship by the scientists, blocked information flows critical to effective regulation, and encouraged crisis response, limitinging medium- and long-rage research projects.[14]

Since the Nader group studied the management of scientists in 1970, current assessments of the situation at the agency would require more research. It does appear that science information flows have improved within the agency and between the agency and the scientific community.[15] Certainly, if further studies indicated that scientific input is still subordinated to administrative decisions, it would represent an intolerable situation. Since scientific knowledge is the heart of the validity and credibility of agency regulation, formal or informal mechanisms that block its effective use must be eliminated.

CHAPTER IV

INFORMATION MANAGEMENT

The scope of the mission of the Food and Drug Administration impacts every citizen of the nation as a consumer of food and drugs, the producer of the products, the scientist studying their effects, or the lawmaker interested in assuring their safety and efficacy. Consequently, the process of regulation by its very nature elicits information flow and communication between the FDA and the several groups affected by its responsibilities. This flow includes not only scientific information, but also informed judgment on how this data should be combined with law to produce regulation.

The agency's management of information, both scientific and "judgmental", can be analyzed from the four viewpoints suggested above: between FDA and the consumer, the producer, the scientist, and the Congress. Finally, the impact of the Freedom of Information Act on the agency can be investigated.

FDA and the Consumer

In the last analysis, the consumer should be FDA's customer. The mission of the agency––to assure consumer protection––is one that is perceived as a vital public good. All regulatory decisions, then should represent the best interests of the consumer and require that the consumer be a vital link in the decision-making process. Traditionally, however, the consumer has not been nearly as well organized, as well informed, or as vocal as the industries regulated by the agency. Current practices of the agency are seeking to include increased consumer participation and several organized consumer groups have become more vocal in their participation in the FDA decision-making process. Specifically, agency-consumer communication appears in these activities: formulation of the regulatory decisions, their enforcement, and increased consumer education.

Once a "new product" reaches the decision-making process at the FDA, the consumer has several opportunities to input to the ultimate decision. Proposed regulations are published in the Federal Register to solicit public comment; responses are filed and on public view in the Office of the Hearing Clerk. In addition, many of the FDA's public advisory committees have a standing membership offered to consumer representatives. Hearings of the committees are, in general, open to the public.[1]

The FDA maintains consumer affairs offices in 31 metropolitan areas around the nation. The consumer affairs officers address interested groups, answer questions, prepare radio and television broadcasts, and relay consumer concerns and opinions back to the FDA.[2]

Any member of the public can also petition FDA to make or change a regulation. Notice of its filing is published in the Federal Register and further comment is solicited.[3]

In terms of its enforcement activities, actions taken by the FDA often originate from complaints made by consumers. It is the consumer's responsibility to report to the FDA any product he feels is mislabeled, insanitary, harmful, or in violation of the law.[4]

Consumer education is vital to help consumers use products wisely and to take advantage of informative labeling and general information about nutrition and health, often available due to legislation or FDA regulation. The education program of the agency includes publication of pamphlets and memos on various aspects of the FDA and the products it regulates; the publication of FDA Consumer, which includes articles on FDA activities as well as general articles on nutrition and health; and television and radio advertisements encouraging correct product use.

The difficult problem of organizing consumer interests has been solved to some extent by the current surge of informed consumer groups impacting the FDA decision-making process. The relative clout of these groups compared to well-organized industry groups can be questioned, but the correct emphasis is clear. The consumer is the ultimate customer, and all FDA activity should assure that the products available to him are as safe as possible and that he has the information necessary (through informative labeling, etc.) to make the best informed judgment on individual benefits and risks.

FDA and Industry

Industry operates in an advocacy role to bring "industry pressure" on the FDA. The current commissioner of the agency, Alexander M. Schmidt, recognized this role and emphasized the efforts of the agency to clarity and codify the administrative and procedural practices of the FDA. Both formal and informal proceedings are encouraged, with proper protocol for both types of communication.[5]

The Commissioner has also spoken out on efforts by manufacturers, in this particular instance in the drug industry, to muddle and confuse the regulatory process with ineffective and unproductive communication.[6] Clearly, with its limited resources, the FDA must depend on its industry interfacing to be as productive as possible, or time and dollars are wasted.

It is to be expected that industry would be reluctant to be entirely candid with the agency commissioned to regulate it, i.e. to inspect its products and rule on their marketability. However, it is in the industry's best interests to be open and candid and to voluntarily comply with regulatory decisions on safety, efficacy, and good manufacturing practices. Not only can this be viewed as an ethical responsibility, but also it will enhance the industries' public image.

FDA and the Scientist

As has been emphasized, scientific information underlies all regulatory decisions. The communication between FDA and the scientist, then, is a vital link in the regulatory process.

Data on the effects of chemicals in man come from many and varied sources. Drug companies submitting new drug applications conduct their own clinical investigations and also contract with other laboratories to produce data. FDA's scientists at the National Center for Toxicological Research conduct studies on long-term effects. In addition, scientists all over the world are conducting studies related to the mission of FDA; the *Toxicology Research Projects Directory* alone lists 2500 projects being performed by 572 laboratories sponsored by 176 supporting groups.[7]

A great deal of scientific data is being generated that must be assimilated by the regulators at FDA. Extensive libraries and computer resources, as well as informal communication, make this data available. There are two problems attendant to this information, however. As was discussed earlier in the chapter on regulation, the scientific data is still often inadequate to make a definitive scientific judgment, and, even when substantial data is available, there is often disagreement among scientists on the meaning and significance of that information.

The other problem arises in the relationship of the agency to the scientists conducting research in the field. Testimony by Commissioner Schmidt and others before the House Subcommittee on Agriculture in 1975 (concerning the Delaney clause) addressed various comments by scientists outside FDA who were critical of the agency. Dr. Lloyd Tepper, Associate Commissioner for Science, emphasized that the scientist can speak in two contexts—as a scientist and as a citizen commenting on the risk-benefit decision.[8] Dr. Constantine Zervos, in the Associate Commissioner's office, contends that the major responsibility of that office is to evaluate and make clear where science ends and opinions begin.[9]

The scientist is the first vital ingredient in the risk-benefit decision on the safety and efficacy of food and drugs. He provides the hard data on which regulatory decisions are based. The FDA is funding only a small fraction of toxicology research at NCTR; other needed data must come from research funded by other groups whose policy decisions are beyond the FDA's control. However, the agency can have the posture that encourages continued funding of projects on health, safety, and nutrition at as high a level as possible. In addition, the FDA must insist that its scientists stay current in the latest techniques and data that impact their work and encourage them to interact with the scientists knowledgable in that area. As much hard data as possible must be available in each regulatory decision.

FDA and Congress

In the past few years, the communication between Congress and the Food and Drug Administration has been tempestuous, intense, and continual.

The Congress has three general forms of oversight: letters of inquiry, hearings, and Government Accounting Office (GAO) reports. In 1975, the agency received 8000 written queries from Congress. Since Schmidt became Commissioner in 1973, the agency has averaged between 35 and 40 formal Congressional hearings a year, before 20 to 25 different Congressional committees. Since 1970, GAO has prepared 45 investigations and reports on various aspects of the FDA.[10]

Inquiries and hearings require extensive time for preparation by agency personnel, and in nearly all cases aim not at praise, but at censure. The FDA Commissioner maintains that the amount of Congressional oversight is excessive and unnecessary; he recommends that Congress act in a more restrained and responsible manner.[11]

Another serious byproduct of the intense Congressional oversight—besides the important consideration that preparation for hearings and reports use resources that could be applied to other agency programs—is the effect on professionals both inside and outside the agency.[12] Scientists at the agency tend to see their decisions, made with the best available data, as a sort of "noose."[13] Highly qualified scientists who might be hired into the agency or might serve on public advisory committees are reluctant to do so with the promise of political harassment.[14]

Schmidt's analysis of the Congressional oversight of the agency seems well-founded. The Food and Drug Administration is a likely candidate for reports and hearings, because its mission is far-reaching and its decisions have such a potential impact. In addition, the lack of that "equation" that would make regulation more precise, makes every legislator, consumer, scientist, and manufacturer a potential expert on the acceptable benefits and risks to be allowed by the agency. A solution to part of the problem might be to restrict the number of committees and subcommittees "eligible" to conduct hearings. In addition, investigations should not just censure, but should provide constructive criticism to the agency on how it might improve its activities.

The Impact of the Freedom of Information Act

As a regulatory agency, the Food and Drug Administration is the recipient and custodian of vast amounts of information, which includes at times "trade secret" types of data. Prior to 1972, the agency policy was to refuse requests for material in its files because of this potential difficulty. With the Freedom of Information Act, this policy has been reversed. Extensive agency information regulations, published on December 24, 1974, will make public 90 percent of the materials in agency files.[15]

In general, the current policy is that all FDA records are public unless specifically exempted by law. The exempt category includes personnel and medical case records, trade secret information, confidential commercial or financial information, active investigatory files compiled for law enforcement purposes, internal FDA correspondence, and FDA correspondence with other government agencies.

Public information includes safety and effectiveness data on drugs and food additives; correspondence with companies, Congress, and the public; internal operating manuals, informal enforcement actions, adverse drug reaction reports, consumer complaints reported by manufacturers as required by law, and requests for information and FDA's responses.[16]

A result of this policy change has been that the agency is receiving requests for information in ever-increasing numbers. The 1977 budget request includes an increase in 10 positions and $180,000 to cope with this expanding responsibility to disseminate information. The number of inquiries the agency will receive in 1977 could exceed 20,000, double the rate of late 1975.[17]

The consequence of the Freedom of Information Act is that the agency is much more visible and accessible to the public. In addition, the cover-up of actions contrary to public interest is discouraged. The scope of the FDA's mission makes this imperative, and continued openness should be encouraged.

CHAPTER V

A LOOK AT INNOVATION

Although the Food and Drug Administration does not have as part of its mission research and development in the area of food and drugs, as a regulatory agency, it can have a powerful impact on the R&D in those industries. In particular, a heated debate in recent years has centered on the impact of drug review procedures upon the rate of drug innovation in the United States.

The drug industry claims the existence of a "drug lag," a complaint that FDA so delays the approval of new drugs through unreasonable application of the Food, Drug and Cosmetic Act that the public is denied the benefit of important medical discoveries which are available in other countries. The FDA denies responsibility for the slowdown, pointing to downward trends that antedated the passage of the 1962 Amendments to the Act and the subsequent growth of the FDA.[1]

Joseph D. Cooper maintains that the data on costs of drug innovation and rates of return on R&D investment signal a probable decline of medicinal discovery in the U.S. The average cost of developing a new drug has soared from $1.3 million in 1962 to $24 million in the past few years, and could rise to $40 million soon.[2]

According to Cooper, the fact that drug innovation has become a rich man's game demands an examination of FDA regulatory purposes and methods. He contends that the extended review requirements prolong time for approval while causing costs to rise alarmingly. To solve the problem, Cooper maintains that the organizational structure should be redesigned to put major emphasis on the surveillance function, while placing investigational checks on new drug trials largely within academia and the medical profession where adequate peer review mechanisms exist. The Food and Drug Administration should make a general judgment of sufficient cause to allow a new drug to move into prescribing channels under strict FDA-industry-profession surveillance. It is with this surveillance that really worthwhile data on safety and efficacy will be obtained.[3]

CHAPTER VI

THE ISSUE OF TECHNOLOGY ASSESSMENT

To achieve its overall objective of consumer portection, the Food and Drug Administration must perform technology assessment for the food and drug technology the agency has been mandated to regulate. During the process of regulation, important determinations stem from not only the immediate impact of the new technology, but also on the effects of that technology which may be indirect, delayed, unintended, or unexpected. These long-term considerations become especially significant in the areas of food and drug technology, where a decision on the allowance of a new food additive, for example, must be based on the scientific judgment from the most current data of the expected long-range impact of the inclusion of that chemical on human diet and health.

The responsibilities of the FDA in its mission closely parallel a limited definition of technology assessment. The process of science and technology operating in the private sector produce food and drug innovations or improvements to meet perceived health and diet needs. The FDA then focuses on assessing these technologies as they impact on national health and safety. The process emphasizes benefits and costs incurred with the new technology; to a lesser extent does it examine large-scale social and economic issues, cultural impacts, or the design of feasible technological alternatives. The assessment information is input to the political process where more subjective judgments are made for social benefits and costs to produce regulatory decisions.[1]

In the assessment of the impact of food and drug technology, the most difficult judgments relate to the long-term effects of chemicals in the environment. In many instances, scientific data regarding the carcinogenicity of a substance, for example, is not available or must be extrapolated from short-term, massive dose studies, where the effects are likely to be quite different from the effects experienced by humans on a long-term, low level exposure basis. The National Center for Toxicological Research in Jefferson, Arkansas, a relatively new laboratory in the Food and Drug Administration, has a primary mission to study the biologic effects of potentially toxic chemical substances found in man's environment with emphasis on these long-term, low dose exposure effects.[2] In particular, the research is designed to:

—determine the basic biological processes involving chemical toxicants in animal organisms,
—develop data which will facilitate the extrapolation of toxicological data from laboratory animals to man, and
—develop improved test methodologies and protocols for the evaluation of potentially hazardous chemicals.[3]

In clinical lifetime studies, large animal populations in a controlled environment are exposed to a low level of a test compound in their diet. Current studies include dose response to 2-acetylaminofluorene (2-aaf) and benzidine. A budget increase for 1977 has been requested to accomodate the expansion of hormone research involving diethylstilbestrol (DES) and estradiol.[4]

Acute/subacute studies are part of a program designed to improve methods for overt or subtle toxic effects, and providing information necessary for further chronic investigations. Typical projects in 1976 include teratogenic studies for the herbicide 2,4,5-T, aspirin, and cortisone; the development of an automatic data system for teratology data; the study of assay techniques and methods development in mutagenic research; and morphology and histology studies to establish baseline pathology data for comparison with data from experimental animals.[5]

Dr. Constantine Zervos, Director of the Scientific Liaison and Intelligence Staff in the Office of Associate Commissioner for Science, views the National Center for Toxicological Research as an effective way for the agency to operate in the gray area between very basic research and the highly practical matters of regulation. Zervos sees the NCTR as an attempt by the FDA to appreciate the need for research on recurrent themes arising in their mission.[6] Scientific information generated by research at NCTR will assist the agency in further regulatory decisions. The time frame of the lifetime studies will, by necessity, preclude immediate results.

In its broadest sense, then, the mission of the Food and Drug Administration to insure consumer protection is one of technology assessment. The regulatory process administered by the agency depends on the assessment by its scientists of the effects of food and drug innovations, both short- and long-term. The National Center for Toxicological Research is a vitally needed research laboratory, not only because it supports FDA's regulatory mission and need for long-term data, but also because it develops basic knowledge on the effects of chemicals in man's environment. In order for NCTR to maintain its scientific integrity and to perform its mission, both the FDA and the Congress must resist any urge to force immediacy onto the laboratory. To conduct meaningful research, the scientists must feel a supportive relationship from the agency and also be assured of persistent funds to conduct the long-term studies. Often the aspects of regulation in the real world demand immediate decisions and immediate answers. To the extent that it is possible, the National Center for Toxicological Research should be shielded from pressure for results, especially results that the agency is seeking to support a particular regulatory decision at a particular point in time.

CHAPTER VII

DECISION-MAKING AND SCIENCE POLICY

FDA's Role in Generating Scientific Data

In general, there are four classes of science performed or sponsored by Food and Drug Administration. The first class consists of the analysis of products at the field level to determine if they comply with existing regulations. The second occurs at headquarters, where FDA scientists review the work of other scientists in order to pass on particular regulatory decisions. Thirdly, scientists perform research on advanced analytic methods to assist in the regulatory process. Finally, scientists at the National Center for Toxicological Research conduct basic research on the long-term effects of chemicals in the environment. Scientists are, broadly speaking, performing a technician's role, oversight, applied research and development, and basic research.

Extramural research sponsored by the agency is used to supplement intramural research at the agency and to gain access to unique resources outside the FDA. For example, contracted studies in 1974 by the Bureau of Drugs were focused on methodology to be used in bioavailability testing and subsequent bioavailability studies on a number of drugs. The Bureau of Medical Devices and Diagnostic Products, with no laboratory facilities of its own, has awarded a contract to the Utah Biomedical Test Laboratory to provide extramural research support for Bureau operations.[1] Contracts are managed by the particular Bureau responsible for the study; the Associate Commissioner for

Science's offices have evaluative power over contract proposals.[2]

FDA research and training grants totaled about $2 million in 1975, and were primarily awarded to universities.[3] Again, the research is pointed toward the gathering of data relevant to the safety and efficacy of FDA-regulated products.[4] The National Food and Drug Advisory Committee recommends grant approvals.[5] Thelma O'Connell of the Extramural Research Staff expects funds for grants to be decreased next year; already 50 to 65 percent of the grant applications approved for funding do not receive money to conduct the studies.[6]

FDA Science Policy—The Use of Science in Agency Regulatory Decision-Making

Science at the Food and Drug Administration is cast in a supporting role of the regulatory decision-making of the agency. This role is not an undesirable or incorrect one. The hard facts of science must underpin all regulatory decisions, but regulation involves much more than generating and evaluating scientific data. Additional constraints of legal requirements, trends in public policy, limitations in resources for research, and interest group pressure are all involved in the FDA decision-making process.

The critical consideration is that science is used in its proper role. It cannot be ignored in the face of administrative or political pressures; neither can data be used to prove something that it cannot substantiate.

The current science policy at the Food and Drug Administration is best described by Dr. Constantine Zervos, in the Office of the Associate Commissioner for Science. He also contends that not all regulation can be based on science. Science has limitations—sometimes there are no means to gain the kinds of answers needed, and sometimes no answers exist. Thus, science, "the high priestess of hard facts," interfaces with public policy and all its attendant emotions and feelings. The important issue becomes, then, the clear delineation of where science begins and ends and where opinions begin as the regulatory process proceeds. Dr. Zervos perceives this function as one of the most important performed by the Office of Science.[7]

CHAPTER VIII

CONCLUSION

The Food and Drug Administration was born out of crisis, and has grown through the years in response to other crises. The nature of the organization itself continues to be reactive. Since its mission is not to do research and development in food and drugs, it must react to those industries' innovations. As questions of safety for residues, additives, pesticides, and others arise, the FDA will attempt to develop methodologies to measure them, and to use scientific data and judgment to quantify possible benefits and risks.

In this environment, then, the science policy of the FDA must center on three critical areas—the proper use of science in the regulatory decision-making process; the effects of regulation on research, development, and innovation in the industries regulated by the agency; and the open and free exchange of information among FDA, industry, and the science community. In the past, it has been found that science is often ignored by officials of the agency as regulatory decisions are being made. This is clearly not in the best interests of effective and meaningful enforcement of the agency' mission of consumer protection; further oversight of the Office of Science should demand the proper place for science. Additional studies should be conducted to determine objectively the impact of FDA regulation on the drug industry and others, and attempt to recommend changes that will promote innovation and at the same time ensure consumer protection. Finally, the current efforts by the agency to be open with information should be encouraged. A posture of this sort will enhance the agency's image and improve its ability to administer its mission with as much information as possible.

FOOTNOTES

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[2] *Ibid.*

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[2] "We Want You to Know About the Laws Enforced by FDA," pamphlet, DHEW Publication No. (FDA) 75-1007.

[3] *Ibid.*

[4] "Information Concerning FDA Regulations," FDA Consumer Memo, DHEW Publication No. (FDA) 76-1008.

[5] "FDA Services Guide," U.S. Government Printing Office: 1974-625-347/13-31, pp. viii-ix.

[6] *Ibid.*, Section II, pp. 1-6.

[7] Hutt, p. 8.

[8] *Ibid.*, p. 10.

[9] "A Consumer Guide to FDA," reprint from *FDA Consumer* (October, 1974), DHEW Publication No. (FDA) 76-1013, p. 5.

[10] Hutt, p. 9.

[11] *Annual Report, Food and Drug Administration, Department of Health, Education, and Welfare, 1974* (U.S. Government Printing Office: 1975-0-599-348; DHEW Publication No. (FDA) 76-1007), pp. 5-6.

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[15] Wayne L. Pines, "Consumer Safety Officers: FDA's 'Front Line'," *FDA Consumer*, VII, No. 9 (November, 1973), 4.

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[17] "FDA Services Guide,", Section II, p. 2.

[18] Hutt, p. 5.

[19] *Ibid.*, pp. 5-9.

CHAPTER II

[1] Senate Committee on Appropriations, *Hearings, Agriculture and Related Agencies, Fiscal Year 1977*, 1976, p. 1052.

[2] *Ibid.*, p. 916.

[3] *Ibid.*, pp. 914-916.

[4] *Ibid.*

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[6] Alexander M. Schmidt, M.D., "Great Expectations or Giving FDA the Dickens," presented before the Health Industry Manufacturers Association, Scottsdale, Arizona, February 2, 1976.

[7] Directorate of Management Analysis, Comptroller of the Air Force, *USAF Summary*, p. FIN-3.

[8] NSF data.

[9] Phone interview with Catherine A. Fitzpatrick, Division of Financial Management, Associate Commissioner for Administration, Food and Drug Administration, March, 1976.

CHAPTER III

[1] Phone interview with Nancy L. Nugent, Staffing and Position Management Branch, Division of Personnel Management, Associate Commissioner for Administration, April, 1976.

[2] Phone interview with George Schwartzman, Assistant to the Associate Director for Planning and Program Coordination, Pharmaceutical Research and Testing, Bureau of Drugs, April, 1976.

[3] Phone interview with Richard Baldwin, Office of Training and Education, Executive Director of Regional Operations, April, 1976.

CHAPTER III—continued

[4] Ibid.

[5] "Chemist—A Career with FDA," DHEW Publication (FDA) 75-1015; "Consumer Safety Officer—A Career with FDA," DHEW Publication (FDA) 75-1017; "Microbiologist—A Career with FDA," DHEW Publication (FDA) 76-1016.

[6] Baldwin.

[7] Ibid.

[8] Ibid.

[9] Schartzman.

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[11] "Food and Drug Administration—Management Intern Program," internal publication.

[12] "Food and Drug Administration—Mid-Level Career Development Program," internal publication.

[13] "Food and Drug Administration—Executive Fellows Program," internal publication.

[14] James S. Turner, The Chemical Feast: The Ralph Nader Study Group Report on Food Protection and the Food and Drug Administration (New York: Grossman Publishers, 1970), pp. 185-201.

[15] Annual Report, FDA, 1974, pp. 1-3.

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[9] Interview with Dr. Constantine Zervos, Director of the Scientific Liaison and Intelligence Staff, Office of the Associate Commissioner for Science, February, 1976.

[10] Schmidt, "Great Expectations."

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[14] Cooper, p. 16.

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[16] Ibid.

[17] Senate Committee on Appropriations, Hearings, Agriculture and Related Agencies, Fiscal Year 1977, 1976, pp. 1052-1053.

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[1] Annual Report, FDA, 1974, pp. 50-53.

[2] Cooper, p. 6.

[3] Ibid., pp. 1-31.

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[1] U.S., Congress, House of Representatives, Subcommittee on Science, Research, and Technology of the Committee on Science and Technology, Science Policy: A Working Glossary, 94th Cong., 2d Sess., 1976, prepared by the Science Policy Research Division, Congressional Research Service, Library of Congress, pp. 83-86.

[2] Annual Report, FDA, 1974, pp. 116-118.

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[3] Senate Committee on Appropriations, Hearings, Agriculture and Related Agencies, Fiscal Year 1977, 1976, p. 1048.

[4] Ibid., pp. 1045–1049.

[5] Ibid.

[6] Zervos.

CHAPTER VII

[1] Annual Report, FDA, 1974, pp. 75–77; pp. 92–93.

[2] Zervos.

[3] FDA Active Research and Training Grants by State, City, Institution, December, 1975, internal publication.

[4] Guidelines for Submittal of Research Grant Project Applications, November, 1975, internal publication.

[5] "Food and Drug Administration Public Advisory Committees: Authority, Structure, Functions, Members," pamphlet, April, 1975, DHEW Publication No. (FDA) 75–1028, p. 4.

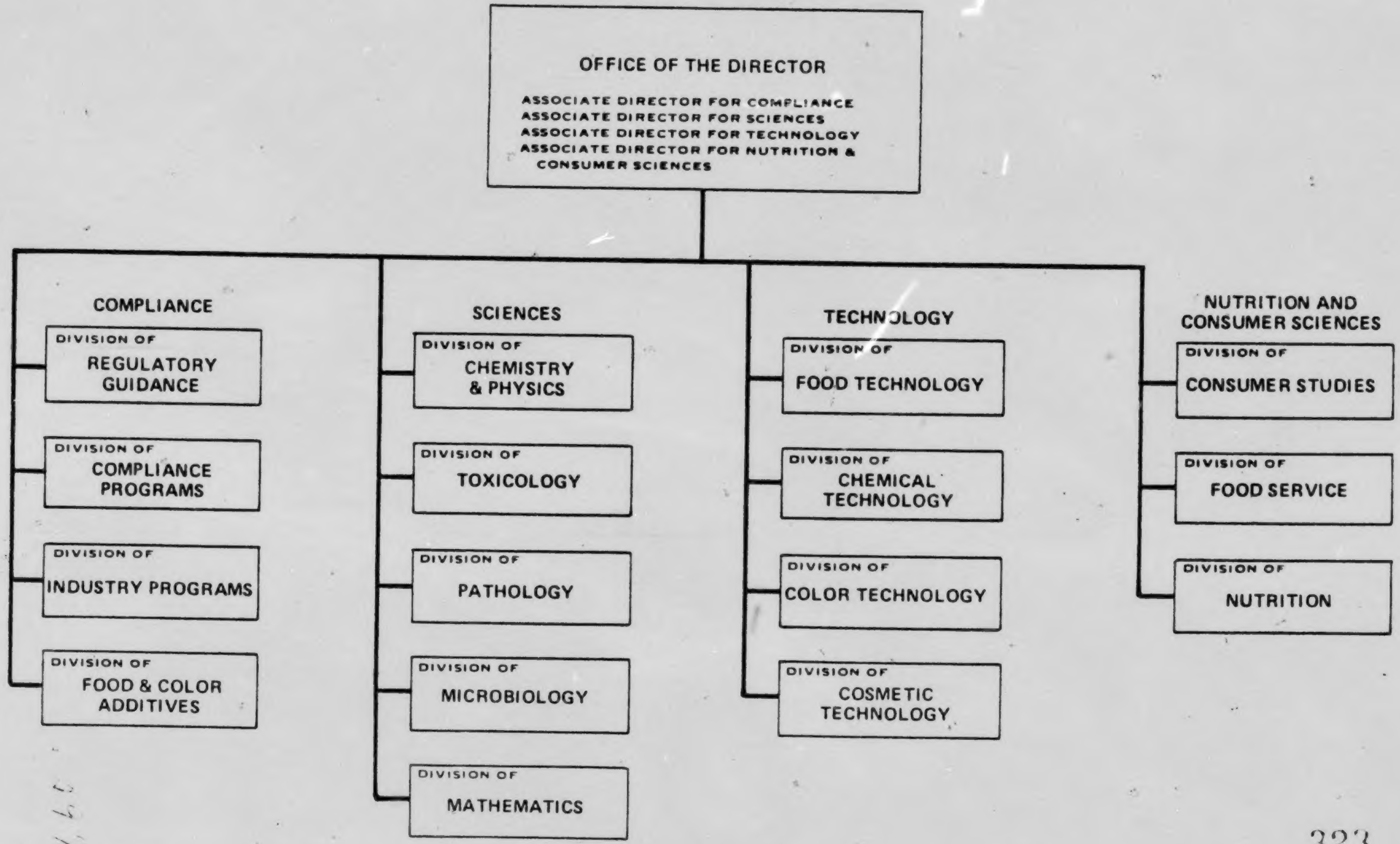
[6] Phone interview with Thelma O'Connell, Extramural Research Staff, Associate Commissioner for Science, February, 1976.

[7] Zervos.

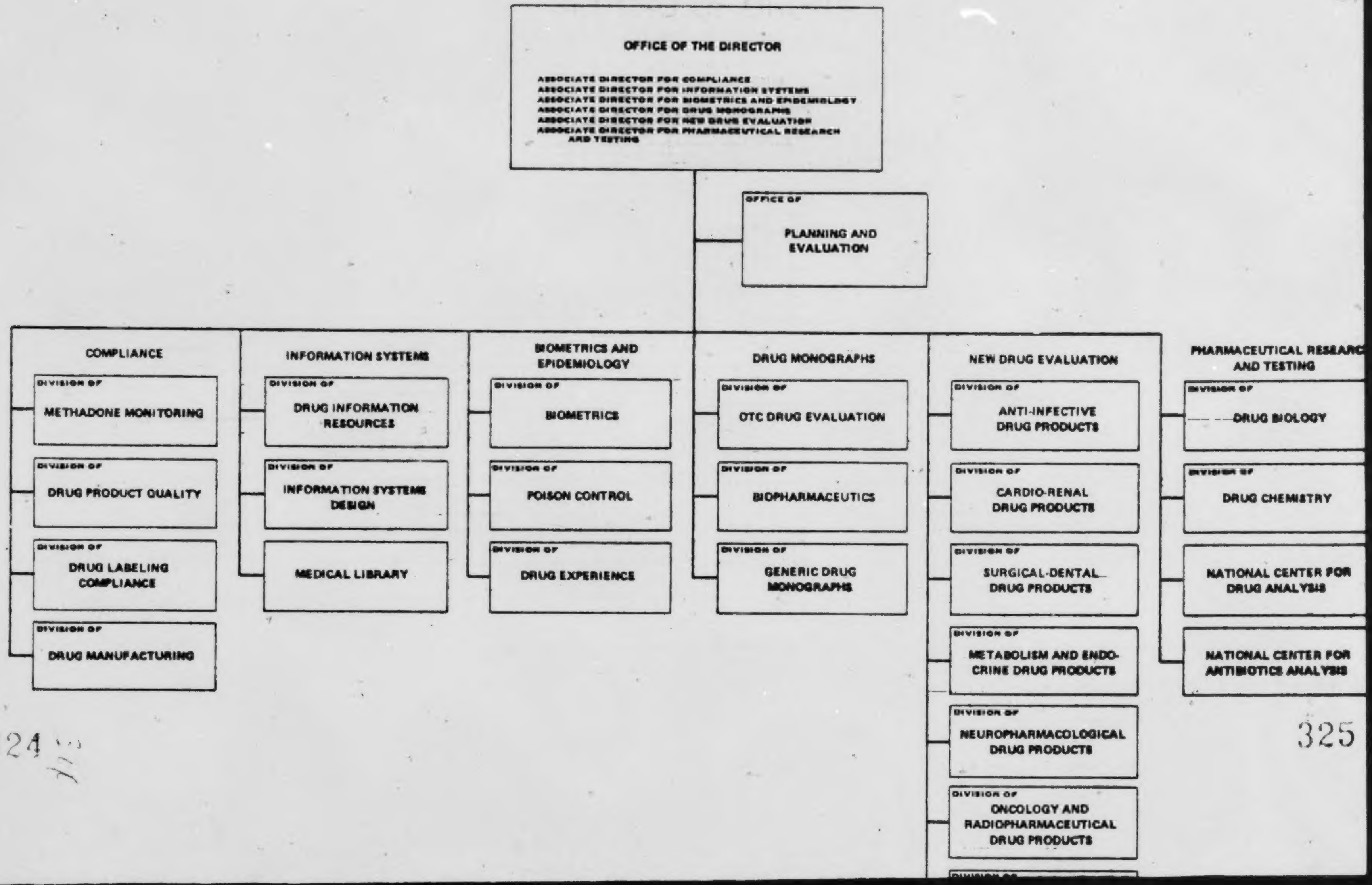
APPENDIX I

FDA ORGANIZATION CHARTS

BUREAU OF FOODS


OFFICE OF THE DIRECTOR
ASSOCIATE DIRECTOR FOR COMPLIANCE
ASSOCIATE DIRECTOR FOR SCIENCES
ASSOCIATE DIRECTOR FOR TECHNOLOGY
ASSOCIATE DIRECTOR FOR NUTRITION & CONSUMER SCIENCES
COMPLIANCE
DIVISION OF REGULATORY GUIDANCE
DIVISION OF COMPLIANCE PROGRAMS
DIVISION OF INDUSTRY PROGRAMS
DIVISION OF FOOD & COLOR ADDITIVES
SCIENCES
DIVISION OF CHEMISTRY & PHYSICS
DIVISION OF TOXICOLOGY
DIVISION OF PATHOLOGY
DIVISION OF MICROBIOLOGY
DIVISION OF MATHEMATICS
TECHNOLOGY
DIVISION OF FOOD TECHNOLOGY
DIVISION OF CHEMICAL TECHNOLOGY
DIVISION OF COLOR TECHNOLOGY
DIVISION OF COSMETIC TECHNOLOGY
NUTRITION AND CONSUMER SCIENCES
DIVISION OF CONSUMER STUDIES
DIVISION OF FOOD SERVICE
DIVISION OF NUTRITION

BUREAU OF DRUGS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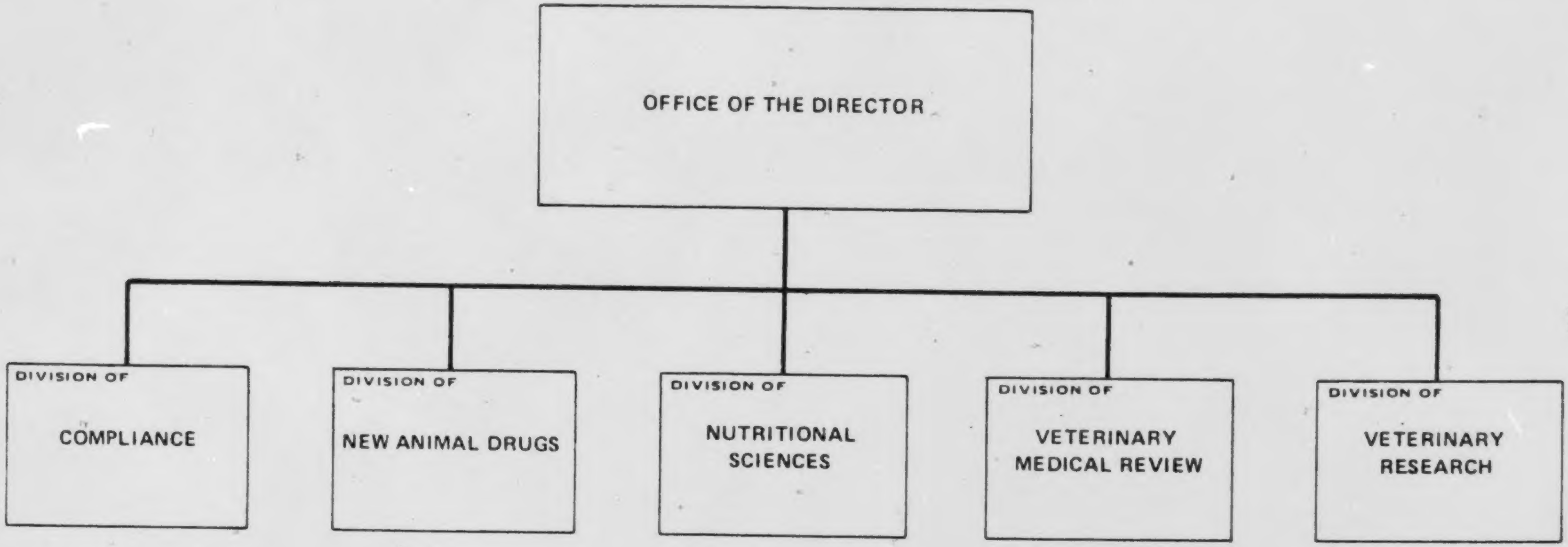
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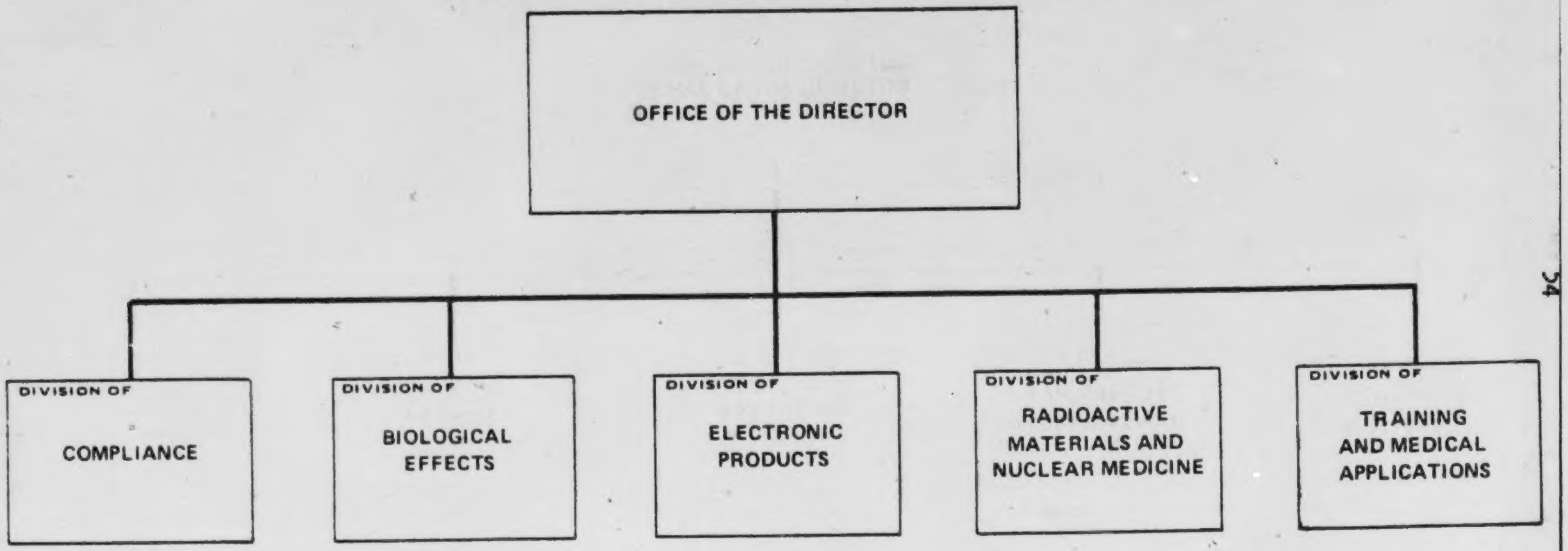
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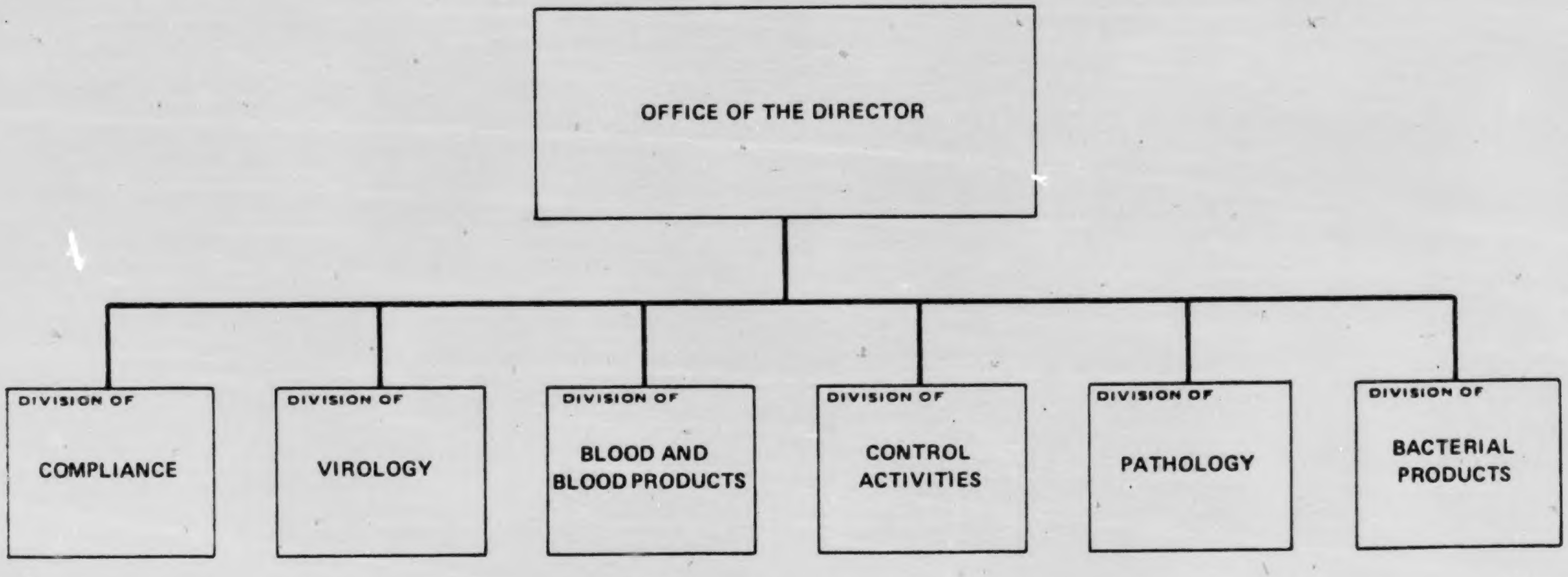
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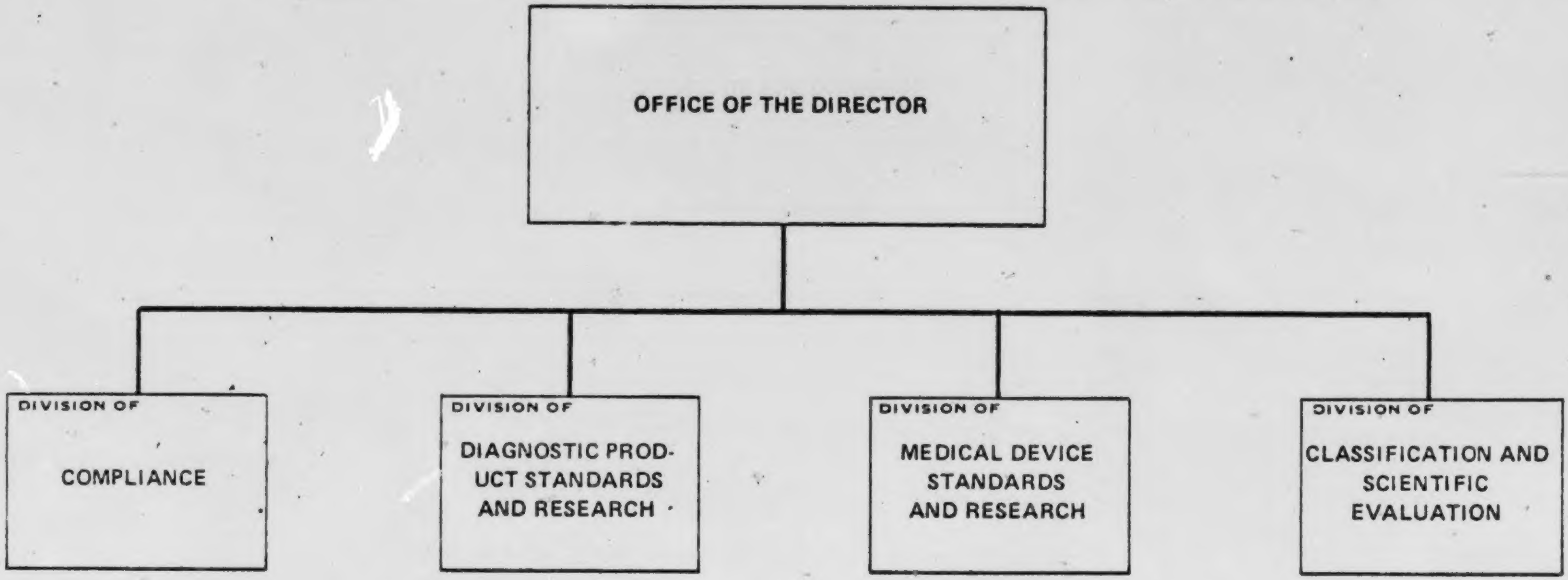
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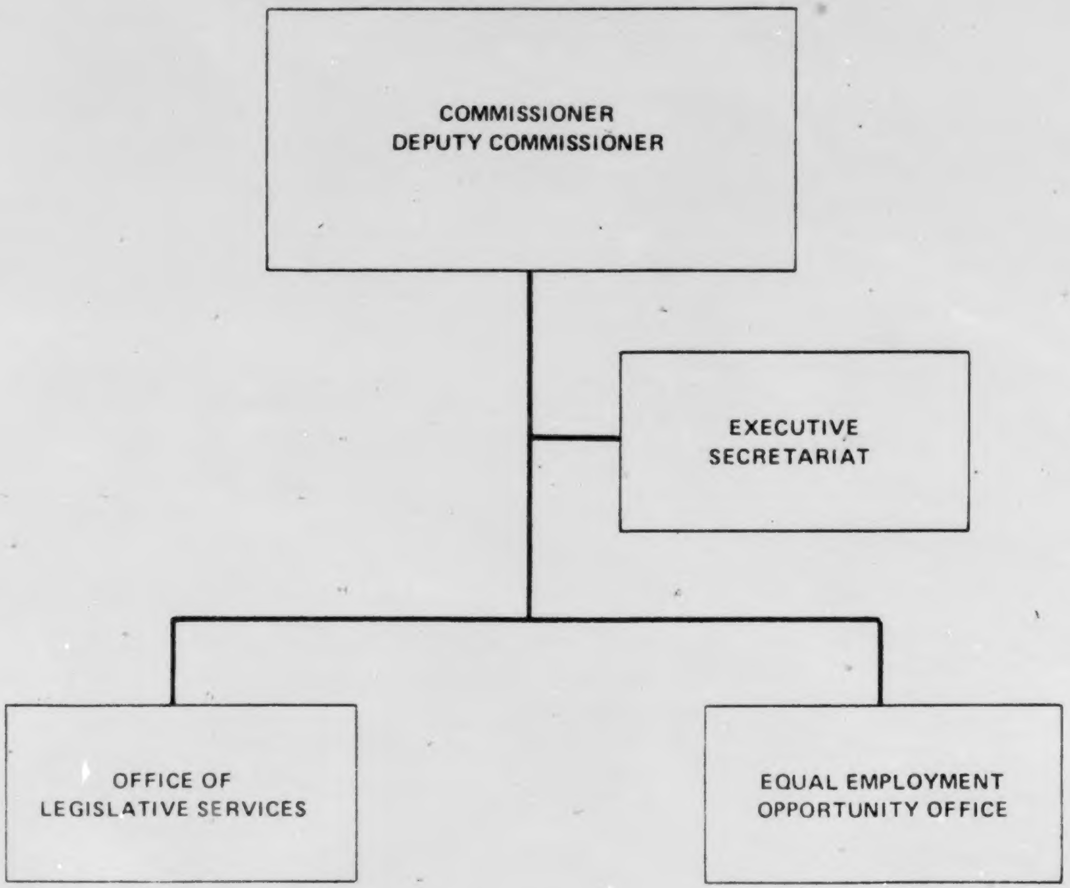
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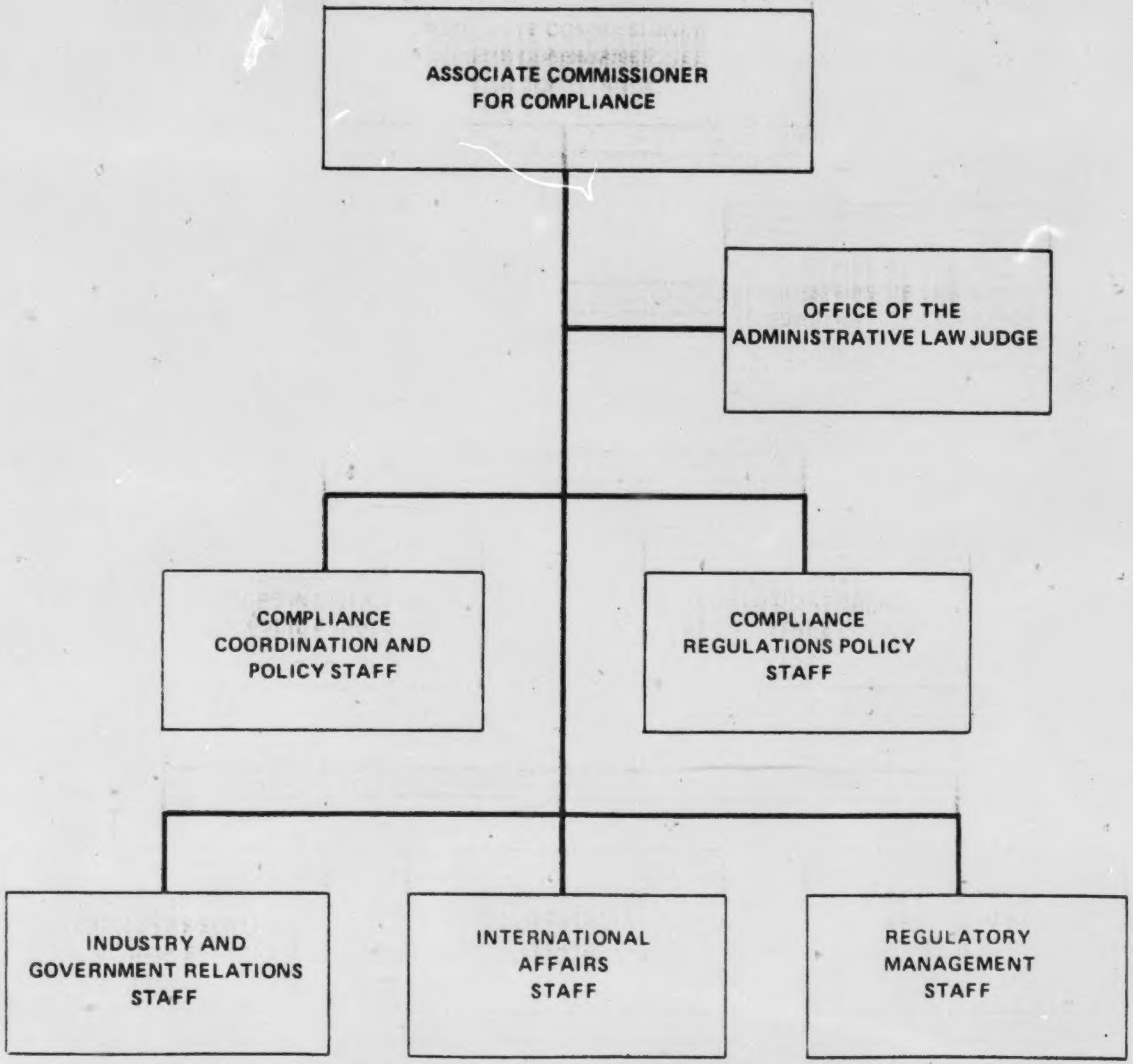
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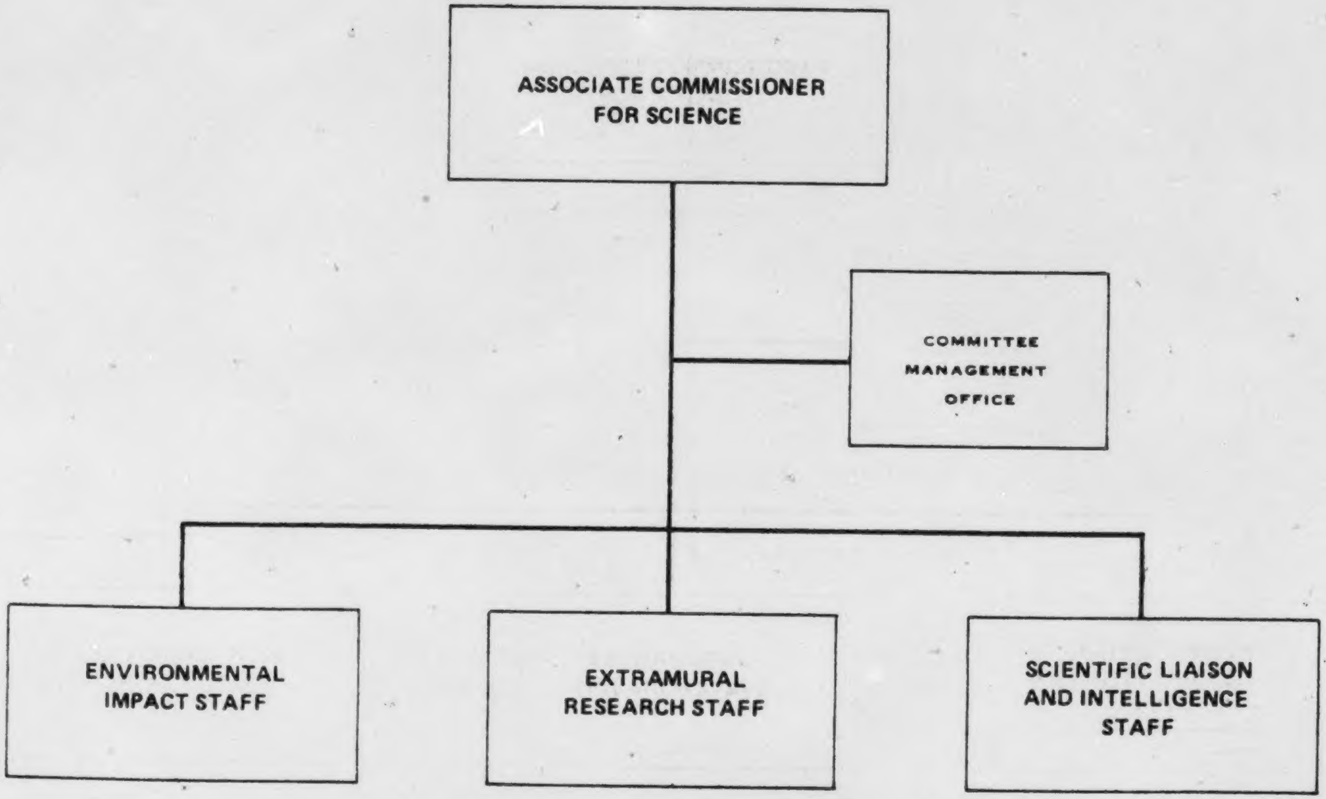
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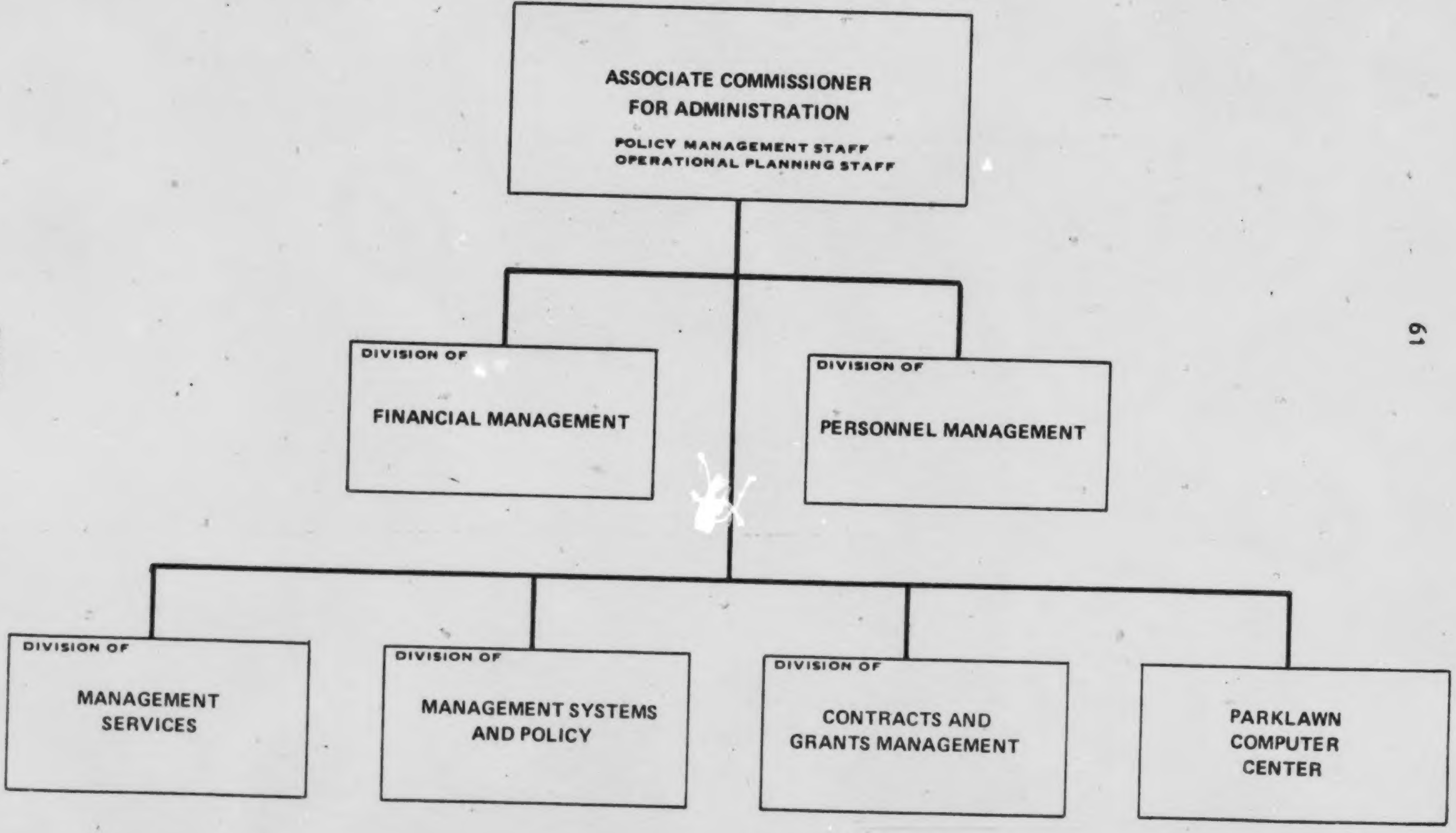
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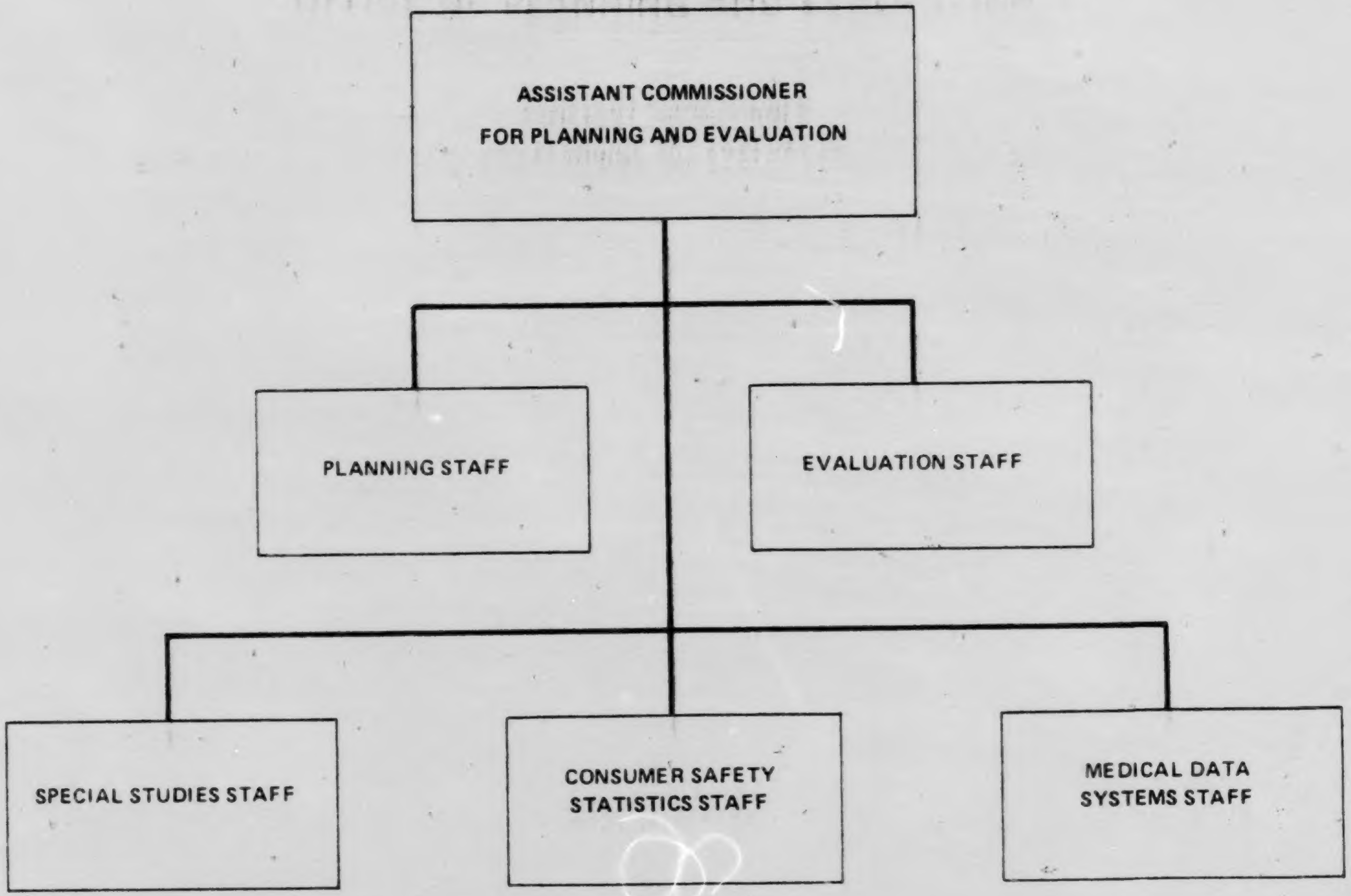
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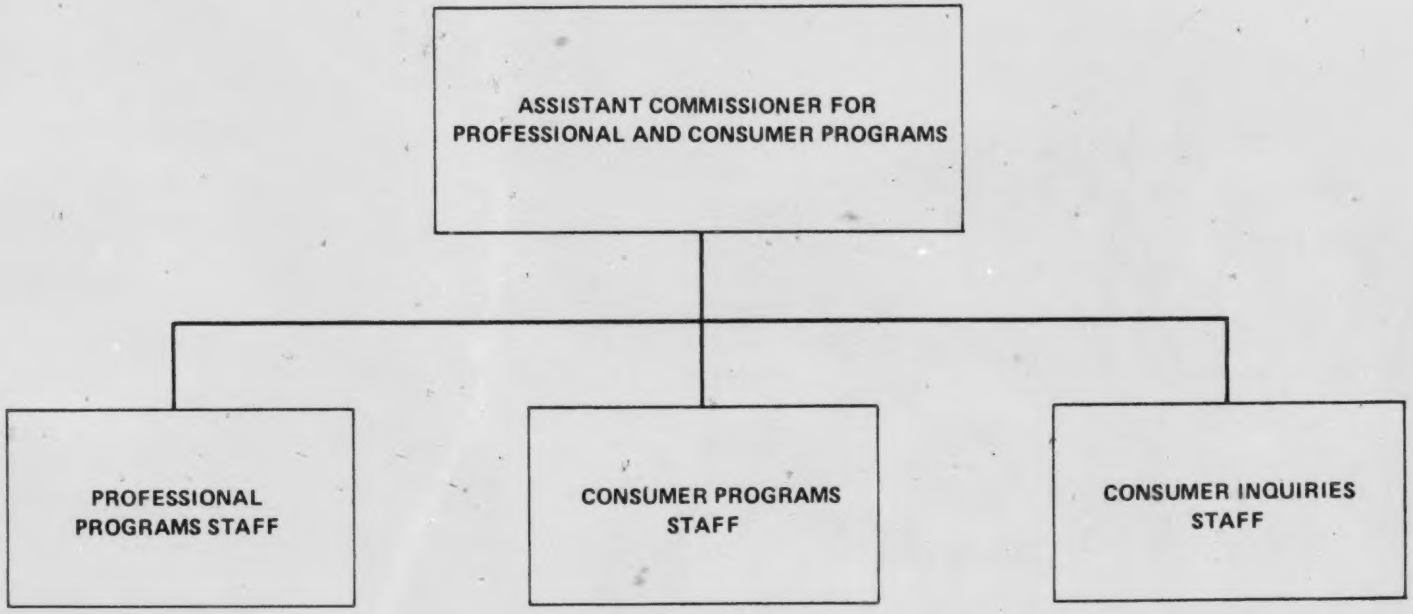
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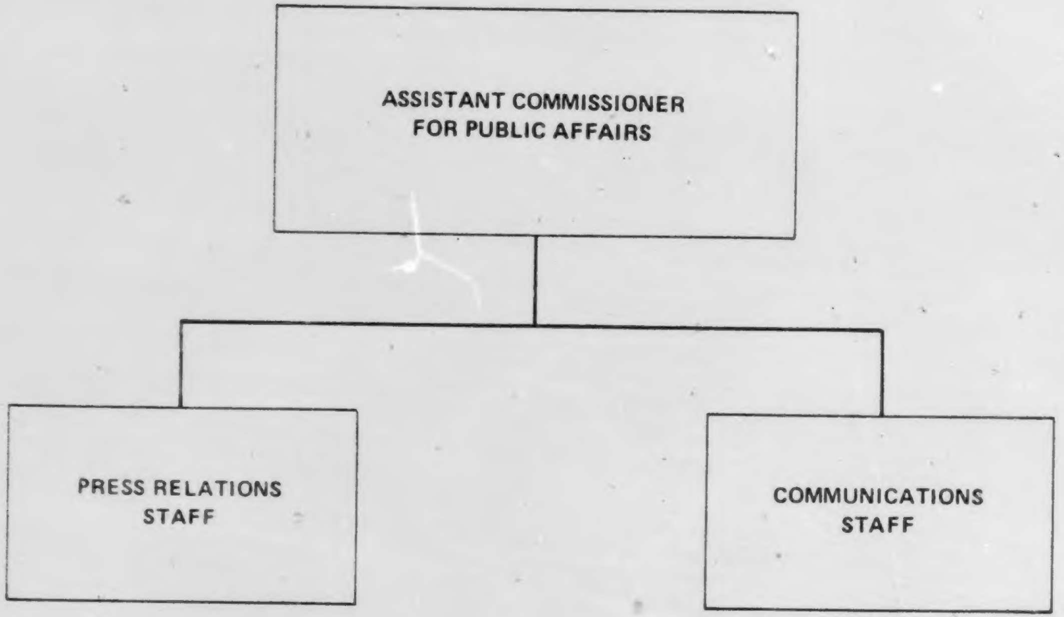
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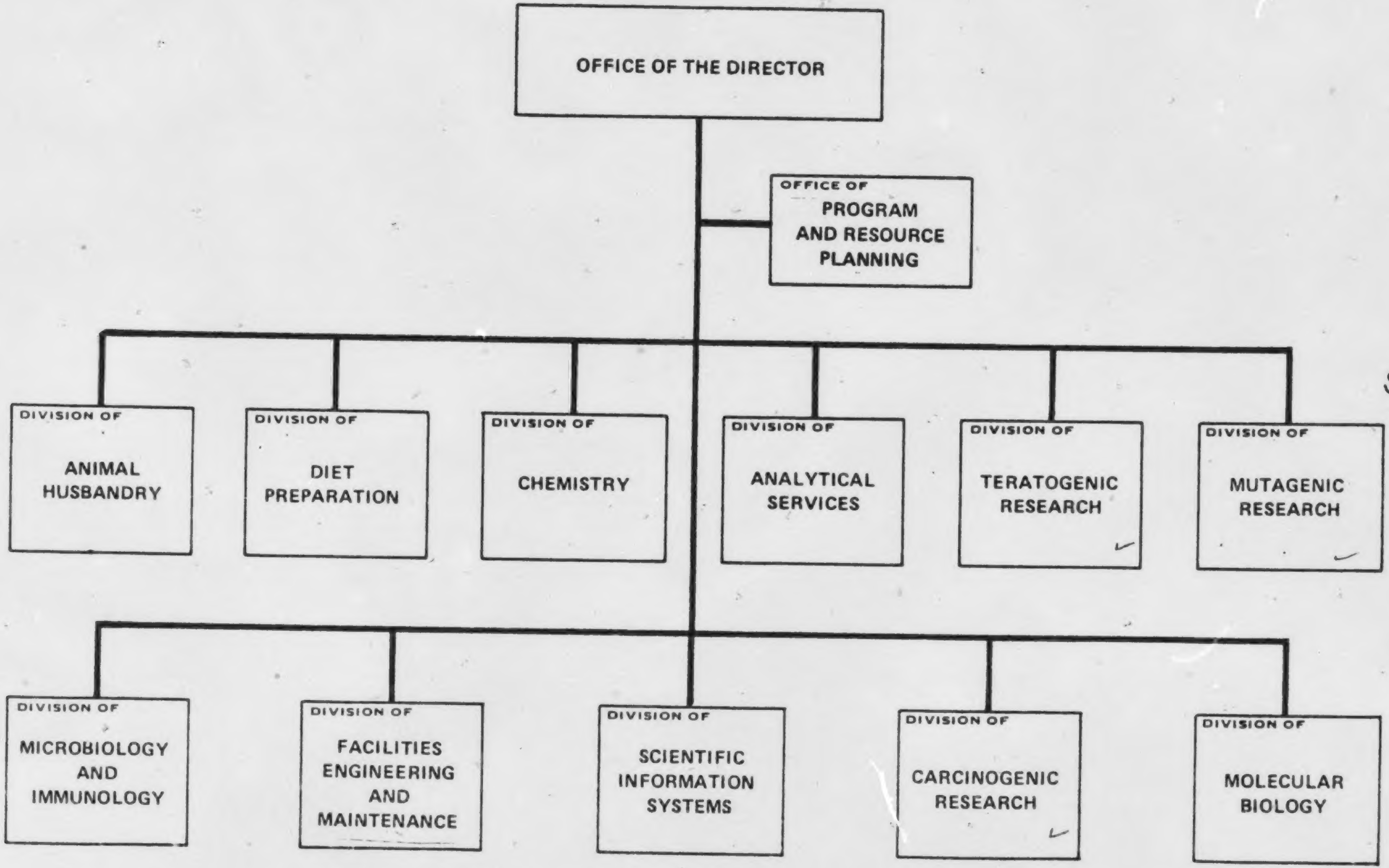
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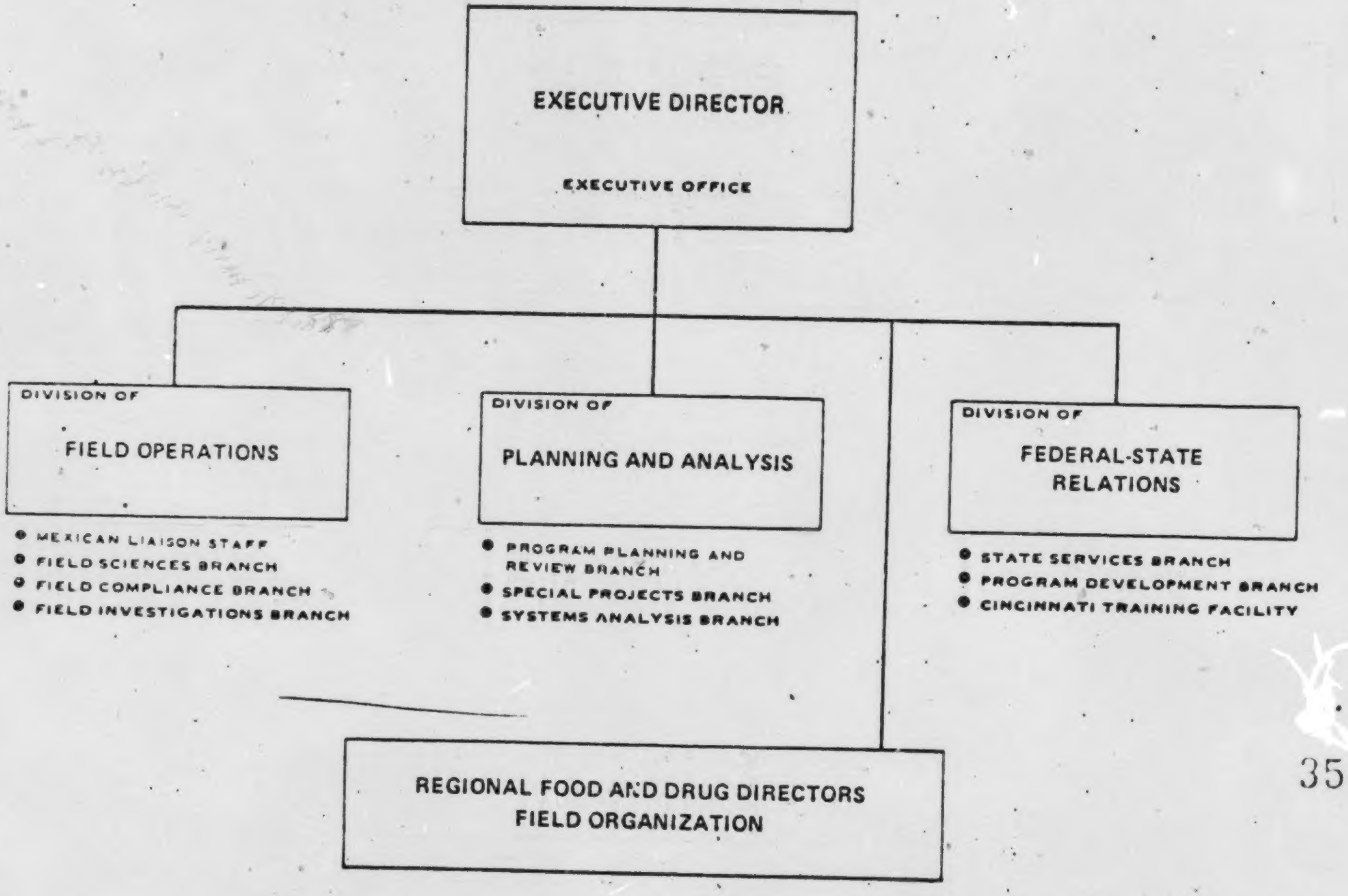
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Thelma O'Connell, Extramural Research Staff, Associate Commissioner for Science.

George Schwartzman, Assistant to the Associate Director for Planning and Program Coordination, Pharmaceutical Research and Testing, Bureau of Drugs.

Constantine Zervos, Director of the Scientific Liaison and Intelligence Staff, Office of the Associate Commissioner for Science.

PUBLIC MANAGEMENT OF SCIENCE:
ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION

by

Duane E. Voeller

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Chapter 1

INTRODUCTION

The purpose of this paper is to present a study in the public management of science. The Federal agency under study was the Energy Research and Development Administration (ERDA) which was created by the Energy Reorganization Act of 1974 and became operational on January 19, 1975. The fact that ERDA is less than one and a half years old was the principal factor in determining the scope of this paper. It was determined that to include a large amount of detail about any particular aspect of ERDA's management activities would be of limited value since virtually every aspect of these activities are in a state of transition and development. As it is, much of the "hard" information presented here can be expected to be out of date soon. Therefore, concentration was placed on the way the organization is evolving in response to the newness and high priority of its mission. In many cases criticisms and shortcomings of ERDA will be raised. However, these should be viewed, not as conditions born of neglect or lethargy, but rather as things left to be done and which are in most cases being actively addressed by ERDA management.

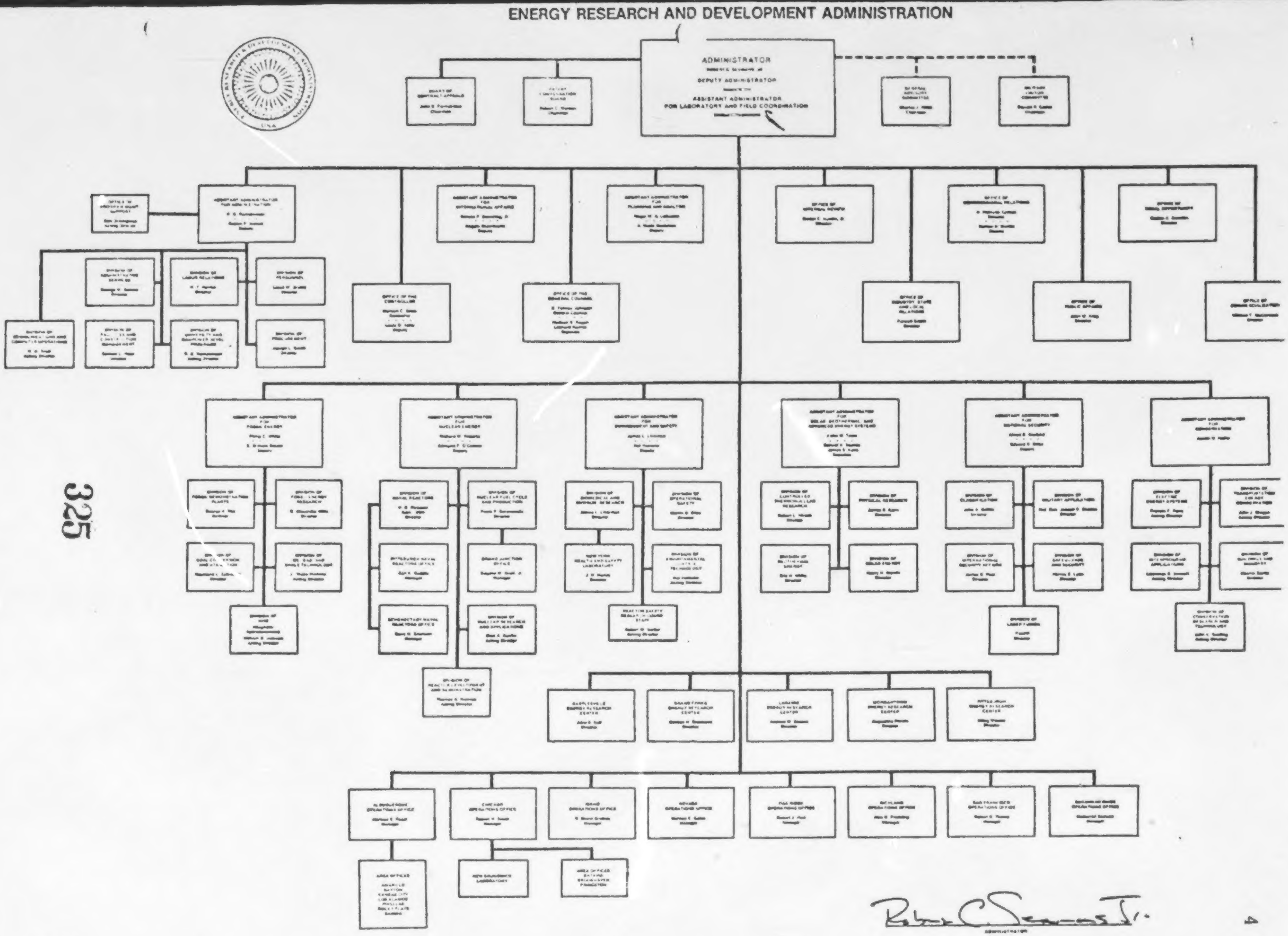
During the course of this study it was assumed that virtually all of ERDA's management activities could be considered "public management of science." Unlike many other Federal agencies whose missions include functions other than the management and utilization of scientific/technical disciplines, the ERDA mission was viewed here to be completely within this realm. This, of course, included the concern for the effects of ERDA's S&T programs on the larger sphere of society and the environment.

The attempt to obtain the latest information on this new and changing organization necessitated contacts with many different persons within and outside of ERDA. Sources of information included special studies, congressional testimony, internal documents and organizational charts, news releases and personal interviews.

Chapter 2

THE ORGANIZATION

The bulk of the ERDA organization came from the Atomic Energy Commission (AEC) but also includes components from the Environmental Protection Agency (EPA), the National Science Foundation (NSF), and the Department of Interior. Figure 1 shows the overall organizational chart of ERDA dated January 19, 1976. It was current as of this writing with the exception that the Assistant Administrator for Laboratory and Field Coordination had become the Assistant Administrator for Field Operations (AFO). As with the Administrator and Deputy Administrator, the six Assistant Administrators for the programatic areas are appointed by the President and confirmed by the Senate. They will be referred to here as the program AA's. The field organization consists of 55 plants and laboratories, five Energy Research Centers (ERC's) and eight Operations Offices with several Area Offices. The ERC's, Operations Offices and the New York Health and Safety Laboratory are staffed by government employees; the remainder are Government Owned Contract Operated (GOCO) facilities. The GOCO


ENERGY RESEARCH AND DEVELOPMENT ADMINISTRATION
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DEPUTY ADMINISTRATOR
ASSISTANT ADMINISTRATOR FOR LABORATORY AND FIELD COORDINATION
ADMINISTRATOR

Robert C. Seamans Jr.

Figure 1. Organizational Chart

arrangement came about as a requirement of the Atomic Energy Act of 1954. Contract employees number about 91,000 with about 51,000 of these being involved in R&D activities, while the ERC's employ less than 800 Federal personnel. The Operations and Area Offices perform primarily administrative functions connected with the GOCO facilities.[1]

Details on the missions and functions of some of the headquarters staff units will be discussed in other sections of this report.

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[1] U.S. Energy Research and Development Administration, Report of the Field and Laboratory Utilization Study Group, Publication #100, December, 1975, pp. 16-17. (Will be cited as the FLU Study.)

Chapter 3

DECISION-MAKING

The purpose of this chapter is to discuss in some detail the method in which ERDA is going about the establishment of its goals and the determination of how these goals will be pursued.

THE PLAN AND PROGRAM

The focal point for the planning effort on the Headquarters staff level is the Office of the Assistant Administrator for Planning and Analysis (APA). The existence of such a focal point is, of course, essential to the integration of effort. However, its existence does not guarantee its effectiveness, especially in the case of an organization such as ERDA in which each of the program AA's possesses a separate mandate as a presidential appointee. The program AA's have established planning groups of their own and have wide discretionary authority over the activities of their divisions. Nevertheless, APA does appear to have developed into an effective, independent planning staff for the Administrator with its work having a great impact on the activities of ERDA as a whole. The official mission/function statement of the APA is:

> Provides independent and objective assessments to the Administrator on technical program issues and on major policy issues; develops, recommends and implements overall policy for planning and analysis activities; establishes standards for and evaluates the planning and analysis activities of program Assistant Administrators; manages and directs the overall Agency planning process including the development, preparation, evaluation, and presentation of summary planning documents; manages and directs broad scope system analysis activities including the preparation of economic and energy related forecasts.

Perhaps the greatest single factor which has determined the influence of this Office on the Agency's activities is its responsibility for preparing a national plan and program for energy research, development and demonstration which is required by the Federal Nonnuclear Energy Research and Development Act of 1974. The initial submission was made to Congress in mid-1975 and will be continually updated.[2] It will be referred to here as the ERDA Plan and/or Program. The first update of the Plan and Program will be published shortly.

Reactions to the Plan and Program from Congress and the private sector have served as the primary guide for ERDA "reform" during the past year. During congressional testimony Deputy Administrator Robert Fri stated:

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[2] U.S. Energy Research and Development Administration, A National Plan for Energy Research, Development and Demonstration: Creating Energy Choices for the Future, Vol 1: The Plan, Vol 2: Program Implementation ERDA Publication #48 (Washington: Government Printing Office, 1975).

> Much of our activity since publication of ERDA-48 (the Plan and Program) has focused on improving our management of energy R&D as well as refining the Plan and Program. For example, we have developed a program planning and control system that will help correct shortcomings noted by the Office of Technology Assessment. Among them will be improvements in our socioeconomic research, basic research, commerical-ization planning, coordination of ERDA and other Federal programs, resource assessments, and international aspects of the ERDA program - all issues raised by OTA.[3]

The program planning and control system of which Mr. Fri spoke is apparently the Program Approval Document (PAD) system developed by APA. During interviews with ERDA officials, several references were made to the PAD which provided them the vehicle to review and comment on proposed programs. "(The PAD) represents a contract between the ERDA Administrator and a program Assistant Administrator and serves as a planning and execution document on a level below (the Plan and Program)."[4] APA is also in the early stages of developing a Plan, Program, Budget and Review system somewhat like that in use within the Department of Defense. APA also develops methodologies to aid particular program areas.

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[3] ERDA News, February 20, 1976, p. 7.

[4] FLU Study, op. cit., p. 54.

One such case was analysis in support of the Assistant Administrator for Conservation to organize projects "so that there will be a timely flow of new technologies producing an early and continuing impact on our nation's efficient use of energy."[5]

Although many criticisms have been directed at ERDA's Plan and Program, many of these have become obsolete. ERDA has been highly responsive to these criticisms. Also, the criticisms came during an early stage of ERDA's existence. Illustrative of this latter situation is a statement by OTA about the Plan and Program:

> The Plan was prepared in the spring of 1975, in the context of ERDA's still-evolving definition of its role and mission. Because of the short time available to ERDA personnel for the preparation of the Plan, the program plans of volume II appear to have been compiled from those of several organizations folded into ERDA.[6]

Because the preparation of the ERDA Plan was a crash project, it "evolved from knowledge and experience readily available to ERDA in its first months of existence."[7] There was no plan for the preparation of the Plan, so to speak. The OTA pointed out that there was inadequate involvement with the States in the formulation of the ERDA Plan, for instance. In the future, State energy agencies will have an opportunity to comment on draft updates of the ERDA Plan before submission to Congress. Contracts with regional organizations are being prepared by APA to provide a mechanism for State input.

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[5] U.S. Congress, House, Committee on Science and Technology, Subcommittee on Energy Research, Development and Demonstration, Statement of Austin N. Heller, Assistant Administrator for Conservation February 4, 1976 (unpublished).

[6] U.S. Congress, Office of Technology Assessment, An Analysis of the ERDA Plan and Program (Washington: Government Printing Office, 1975) p. 15.

THE BUDGET

The ERDA budgetary process will be dealt with here only to point out the constraint that the budget puts on the planning process and the establishment of priorities. The degree of budget juggling which sometimes occurs between the Office of Management and Budget (OMB) and the Congress would tax the most well conceived planning process. A few extracts from congressional testimony should suffice to illustrate the point. Before that, however, it should be pointed out that while the bulk of ERDA's programs and resources were inherited from the AEC, the difference in the missions of the two agencies is vast. These two factors have given rise to charges on many fronts that ERDA has not given a high enough priority to the development of non-nuclear energy technologies as reflected in the ERDA budget. ERDA's answer to these charges seem to have been basically two:

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[7] ERDA Plan, op. cit., p X-1.

(1) The nuclear programs which were transferred to ERDA were much more advanced than the non-nuclear programs and for the most part had reached the demonstration stage, the most expensive stage in the R,D&D cycle and,

(2) ERDA funding of non-nuclear programs is consistent with the efficient use of resources.

During congressional testimony on the Liquid Metal Fast Breeder Reactor (LMFBR) ERDA stated:

> Continuation of the LMFBR program does not imply that other alternate energy systems will not be pursued vigorously and at their optimum pace. The ERDA program contemplates increases in funding for non-nuclear energy R&D of several hundred percent over that expended just two years ago. Anyone conversant with the problems of expanding R&D programs will agree that this rate of funding increase is near the maximum consistent with efficient use of funds.[8]

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[8] U.S. Congress, House, Committee on Interior and Insular Affairs, Subcommittee on Energy and the Environment, Oversight Hearings on Nuclear Energy - Nuclear Breeder Development Program, Hearing, 94th Congress, 1st Sess., June 2, 5, & 6, 1975 (Washington: Government Printing Office, 1975) p. 18.

However, the argument goes further than this. The effect that OMB has had on ERDA funding in the non-nuclear area was enunciated by Senator Frank Church:

> Congress mandated that ERDA embark upon a crash program in developing non-nuclear energy alternatives. This "business as usual" budget (coming from OMB) raises serious questions.[9]

The ERDA Plan stated:

> Enhanced recovery (of oil and natural gas), which requires some technological development, will buy roughly 10 years of time. These 10 years are crucially important to the country because they double the time available for the development of new energy sources.[10]

And yet the Administration had requested $8M less than this program had received the previous year. OMB had also cut the ERDA budget request in half for coal and oil shale technologies and geothermal and solar energy R&D.[11] During the same hearings the National Rural Electric Cooperative Association stated:

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[9] U.S. Congress, Senate, Committee on Interior and Insular Affairs, Subcommittee on Energy Research and Water Resources, Opening Statement of Senator Frank Church on FY 77 ERDA Authorization Request, February 23, 1976 (unpublished).

[10] ERDA Plan, op. cit., p. S-3.

[11] Church, loc. cit.

> While research recommendations seem to receive full staff support, ERDA budget recommendations, which must receive prior approval of the Office of Management and Budget, often do not reflect this same need and urgency in terms of money allocations. It seems to us that OMB, with only a handful of "technical experts" may be exercising undue control over projects within the ERDA budget, and therefore the energy future of this nation.

And Dr. Ronal W. Larson, Professor at the Georgia Institute of Technology testified:

> This year, (the Assistant Administrator for Solar, Geothermal, and Advanced Energy Systems) chose to resign rather than to defend (the solar budget) again. From personal conversations with (him), I believe that his decision to resign was based more on the process, rather than on the size of the budget. ...As the principal spokesman for ERDA on its Solar Program, (he) apparently did not have authority over even the smallest portion of the Solar Budget he had to defend. These decisions are the prerogative of OMB.

ADVISORY COMMITTEES

ERDA currently has ten advisory committees reporting to it. The following is a listing of these committees and their respective areas of concern:[12]

(1) Advisory Committee on Geothermal Energy: geothermal energy.

(2) Atomic Energy Labor-Management Advisory Committee: radiological aspects of industrial safety.

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[12] From charters for ERDA Advisory Committees.

(3) Committee of Senior Reviewers: security classification and declassification of scientific and technical information.

(4) General Advisory Committee: general scientific and technical matters.

(5) General Technical Advisory Committee: research on mining, preparation, and utilization of coal.

(6) High Energy Physics Advisory Panel: high energy physics research.

(7) Historical Advisory Committee: historical works on ERDA.

(8) Lignite Advisory Committee: consultant to Grand Forks ERC.

(9) Procurement Policy Advisory Committee: ERDA procurement policy.

(10) Task Force on Demonstration Projects as a Commercialization Incentives: as name implies.

It is not possible to analyze the actual influence of each committee on ERDA policy and planning with the information available at this writing. It is noted, however, that the advisory committee system is still evolving and this list cannot be expected to remain current for long.

Chapter 4

INNOVATION

This chapter is divided into three somewhat overlapping sections. The sections address the factors relating to innovation by (1) scientists and engineers as individuals, (2) organizational elements within ERDA, and (3) the organization as a whole in its relationship with other parties in the technology transfer process. The latter of these will receive a fuller treatment than the others, largely because the technology transfer process is the essence of the ERDA mission and there is much readily discernible activity in this area. The subjective nature of innovation by individuals or organizational elements makes it much more difficult to deal with, especially in an organization as large as ERDA. Virtually any statement that could be made about the subject could surely be shown to be non-applicable to at least part of the organization. For this reason, a very general treatment is given here.

INDIVIDUALS

Elsewhere in this paper, factors which affect the quality and performance of the Agency's scientific personnel in an indirect way are discussed. The factors include the nature of the organization and planning and control practices. In this section, factors which affect the quality and performance of ERDA's S&T personnel in perhaps a more direct way are treated.

As was indicated in Chapter 2, the majority of these people are employed in the GOCO facilities and it is one of the responsibilities of the contractors to obtain and retain high quality individuals and create an environment which is conducive to high performance. Each of these contractors has its own style for doing so. However, even under these circumstances, ERDA management is highly influential in this regard. The Management assigns the missions and programs to the field organization and, thereby, the framework within which the individuals perform.

It seems reasonable to correlate performance with innovation since innovation is the essence and the goal of scientific work. The FLU Study pointed out that "the laboratories and Energy Research Centers are expected to be scientific and technical resources of the highest quality, broad, flexible, responsive to national needs, and a source of innovative concepts for meeting those needs."[13] As for the quality of the technical staff itself, it was noted that the glamor of the AEC's mission, generous funding and favorable management practices attracted a considerable share of the Nation's most eminent scientists and engineers. The FLU Study went on:

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[13] FLU Study, op. cit., p. 37.

> A certain waning of the glamor of the Atomic Energy Commission mission with the passage of time and the increased administrative clutter of an aging bureaucracy have contributed over the past years to a slow erosion of laboratory quality. This erosion can now be compensated by the urgency of the broader mission that has been given to ERDA, and by appropriate management policies.[14]

One of these management policies was noted to be the support of basic research which allows the laboratories "to retain scientists of the highest quality, enriching the array of available talents and providing a strong bond with the university community."[15] As for the Operations and field project offices, the FLU Study found that low moral seemed to be associated with "a feeling of lack of involvement and an uncertainty in priorities and missions."[16] Organizations which had clear cut missions and which were achieving discernible results seemed to be maintaining a high morale. Further:

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[14] Ibid.

[15] Ibid.

[16] Ibid., p. 39.

> The generally lower government grade structure in the field, compared to ERDA Headquarters, affects the ability of the managers to attract and retain quality personnel. This fact also inhibits the assignment of senior ERDA Headquarters people to the project and Operations Office organizations.[17]

In general, the Operations Offices were found to lack technical capability.

ORGANIZATIONAL ELEMENTS

Although ERDA is a new agency, most of its component parts are not, particularly in the field organization. The innovative challenge to ERDA Headquarters elements will largely involve the refinement of the ERDA Plan and Program and the coordination of the field organization for the implementation of the Plan. There are 55 plants and laboratories, five Energy Research Centers, and eight Operations Offices. The task of establishing a complex of facilities such as this under a completely new organizational plan would be difficult in itself. However, to begin with already existent facilities, each with its own inertia or momentum, as the case may be, has made the task formidable. The FLU Study found that ERDA, after its first year of operation, still faced the problem of mobilizing its vast resources in a concerted way. A few of the FLU Study findings revealed, at least in the eyes of the Study Group, some of the specific difficulties yet to be overcome:

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[17] *Ibid*.

> (1) Effective use of the technical and management capabilities of the field organizations is often impeded by uncertainty at headquarters about their potential.
>
> (2) Although the diversity of management practices in the present headquarters-field relationships is often justified, there is a lack of overall strategy for the use of the entire field complex which leads to inefficient practices.
>
> (3) There is a lack of clear delegation to the field of responsibility for project execution, and insufficient flexibility to carry out assigned missions and to explore new concepts.[18]

This last point received much attention by the Study Group, which maintained that the field organization should have greater responsibility for carrying out ERDA's programs. It was recommended that the Operations Offices manage projects in the engineering development and demonstration categories, while the laboratories and Energy Research Centers assume clearly defined areas of responsibility in the research and technology development categories with much more freedom to carry out their missions than is currently the case. This, after joint initial planning of the scope of effort with Headquarters.[19]

The method of funding R&D activities was found to give most laboratory and ERC directors very little "independent authority or flexibility to be responsive to diverse program initiatives originating during a fiscal year."[20] On the other hand, laboratories with broad supporting research programs with funding in large blocks allowed the directors to support a new research idea at an early stage.

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[18] *Ibid.*, p. 8.

[19] *Ibid.*, p. 9.

TECHNOLOGY TRANSFER

Technology transfer/commercialization is at the core of ERDA's mission. This is technology transfer in its broadest meaning. Although definitions of technology transfer abound, they usually refer to the transfer of existing technologies, developed under Federal R&D funding, to State and local governments or the private sector. The FLU Study noted that technology transfer often applies to a technology developed in one field being applied to a second unrelated field.[21] Neither of these situations is appropriate to describe ERDA's responsibility for technology transfer. ERDA's goal must be to develop energy technologies which from the beginning are intended to be moved into the marketplace. Probably the most important ramification of this goal is the need to encourage the participation of industry, as well as State and local governments, at a very early stage of the energy R&D

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[20] Ibid., p. 38.

[21] Ibid., p. 31.

planning. Also, the Agency must be ready to support promising energy R&D initiatives coming from the private sector. This will necessitate breaking new ground because it has never been done before, at least not on a scale such as will be needed to have a major impact on the Nation's energy supplies.

Statutory provisions for ERDA's responsibility in this area are contained in the Energy Reorganization Act of 1974:

> (Responsibilities of the Administrator shall include) participating in and supporting cooperative research and development projects which may involve contributions by public or private persons or agencies, of financial or other resources to the performance of the work; (and) developing, collecting, distributing, and making avialable for distribution, scientific and technical information concerning the manufacture or development of energy and its efficient extraction, conversion, transmission, and utilization.[22]

Also:

> ...the Administrator is authorized to make arrangements (including contracts, agreements, and loans) for the conduct of research and development activities with private or public institutions or persons, including participation in joint or cooperative projects of a research, developmental, or experimental nature....[23]

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[22] U.S. Congress, House, Committee on Science and Technology, ERDA Authorization 1976 and Transition Period - Overview, Hearing, 94th Congress, 1st Sess., February 6, 1975 (Washington: Government Printing Office, 1975), p. 3.

[23] *Ibid.*, p. 7.

An excellent example of how these provisions can be utilized is the case of a physicist who had formed his own company for the development of a highly efficient, long-life light bulb but lacked sufficient finances. ERDA agreed to fund the project (at about 90%.) ERDA will own any patents resulting from the work but in turn will be able to license private concerns for the production of the bulbs.[24]

In this case ERDA was the passive party; the inventor, the active. Much new ground needs to be broken in order to *actively* encourage broader industrial participation and to streamline the process in general. Two of the FLU Study findings are particularly noteworthy in this regard:

> (1) The participation of industry in the process of commericalization of new energy approaches is impeded by legal and administrative roadblocks; some of these also inhibit industry-laboratory interactions.
>
> (2) Key factors in the commercialization process have not always been identified, and clear assignments of responsibilities to the field organization have not generally been made in the technology transfer process.[25]

The OTA had similar comments.[26] The ERDA Plan, as updated, promises to focus greater attention on developing mechanisms for helping the private sector commercialize new technologies.

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[24] *Washington Post*, March 6, 1976, p. 1.

[25] FLU Study, *op*. *cit*., p. 8.

[26] OTA Analysis of ERDA Plan, *op*. *cit*., p. 35.

ERDA Technology Transfer Assignments

An attempt to determine which offices in ERDA had responsiblity for managing technology transfer activities proved to be a rather complicated matter. Responsibility in this area spreads virtually across the board. ERDA clearly is expending much effort to rectify the shortcomings noted above but this appears to be a "scatter gun" process, at least from the outside. In any case, information obtained from several ERDA officials, notably Mr. C. B. Smith, Assistant Director for Research Application, Office of Industry, State and Local Relations (ISL), goes far in explaining the current ERDA approach to fulfilling its technology transfer mission.

Each of the program Assistant Administrators has the responsibility for the transfer of the technologies developed within his activity. This includes such things as determining user needs, developing a transfer plan, performing technical and economic evaluations, and recommending incentives. The Office of the Assistant Administrator for Planning and Analysis (APA) will develop analytical techniques (methodologies) and conduct independent program evaluations for the Administrator. The field organizations will support the technology transfer activities of the program AA's as requested and provide "ERDA presence" throughout the Nation. (More about this below.) Within ISL is the small but high level staff of the Assistant Director for Research Application. The activities of this Office may be viewed as academically oriented, providing information and guidance to other ERDA elements concerning technology transfer. The official mission/function statement of this Office is, "Plans and directs those activities related to R&D commercialization, the transfer of ERDA technology spinoff, and the evaluation of energy related inventions submitted to ERDA or the NBS."[27]

So far, so good. But what about the Office of Commercialization? This Office was established on January 21, 1976 and its official mission/function statement is:

> Assists the Administrator in focusing the ERDA's efforts toward moving new or available energy technologies into the commercial marketplace by examining constraints to the commercialization of these new or available energy technologies and analyzing the effectiveness of various incentives to overcome these constraints.[28]

Yet it has been stated that "this Office will assume responsibility for active (author emphasis) commercialization of selected technologies as assigned."[29] Also, this would seem to overstep the responsibilities of the program AA's.

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[27] From ERDA organizational chart of ISL.

[28] From ERDA organizational chart of the Office of Commercialization.

Some background information helps to see how this situation came about. During December 1975 it was announced that ERDA planned to set up a separate unit for its synthetic fuels program which would move it into the demonstration phase.[30] The new unit would be at the program AA level. Later that month, Dr. William T. McCormick, formerly of OMB, joined ERDA as Deputy Assistant Administrator for Synthetic Fuels Commercialization.[31]

However, Congress failed to approve funding for this program which included large loan and price guarantees and construction grants to industry as an incentive for its involvement. Dr. McCormick then became head of the new Office of Commercialization. ERDA's request for funding of the synthetic fuels program has been resubmitted and is pending before Congress. It will be interesting to see what happens to the Office of Commercialization if this funding is approved.

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[29] C. B. Smith, Technology Transfer Function in Laboratories (unpublished talk delivered to Senior Laboratory Management Committee, ERDA, February 11, 1976.)

[30] ERDA News, December 5, 1975, p. 1.

[31] ERDA News, December 19, 1975, p. 1.

Field Organization Participation

As for the participation of the field organization in the technology transfer process, the FLU Study stated:

> ERDA's energy mission requires sensitivity to regional requirements, an ability to maintain close, continuous liaison with commercial and private organizations; a convenient contact point for inventors; and an effective liaison with local, state, and regional governments and the public.[32]

The establishment of "ERDA Centers" was recommended. The ERDA Centers would have responsibility for ERDA activities within an assigned region of the U.S. Following this recommendation the Assistant Administrator for Field Operations established an in-house task force to plan a system of ERDA Centers. The Regional Task Force report has been approved by the Administrator and now is in a very early stage of implementation.

A further effort to expand the technology transfer activities of the field organization was outlined in a presentation by ISL to the Senior Laboratory Management Committee. In this presentation, some definitions were given:

> Commercialization is the transfer of ERDA sponsored R&D the the commercial sector. Technology Utilization is the application of ERDA sponsored R&D to nonprogrammatic application in the commerical sector. Technology Transfer is the umbrella term which covers transfer irrespective to the relationship between the application and purpose for which the Research was undertaken.[33]

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[32] FLU Study, op. cit., p. 49.

[33] Smith, op. cit.

Within the laboratories there exists a Technology Utilization (TU) Program which has facilitated spin-off applications of technologies developed by the program AA's. The intent of ISL is to encourage the expansion of the TU agents' function into the commercialization effort:

> This means that the TU agents will be functioning not only with respect to the spin-off effort (which may in fact become the minor part of their effort), but also to the main line commercialization planning which goes on at the Lab level. To this end, ISL is immediately commencing a program of background building for the TU agents.[34]

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[34] Ibid.

Chapter 5

TECHNOLOGY ASSESSMENT

The definition of technology assessment used in this paper is: The identification and study of the secondary or indirect impacts of a technological development on the environment and society, that is, the unintended, unexpected, or delayed consequenses of the implementation of the technology. The identification of ERDA's activities in this field was complicated by the fact that the plans and programs which could, at least in part, be considered as technology assessment have not been explicitly delineated as such. An OTA study of the 1976 ERDA budget raised the following questions:

> How does ERDA view the role of technology assessment in its total mission? Should some percentage of the budget be designated for technology assessment?[35]

The study could only point out that "evidence for ERDA activity...in assessments of the impacts on society and the environment of energy technologies, occurs in several places in the ERDA budget..."[36]

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[35] U.S. Congress, Office of Technology Assessment, An Analysis Identifying Issues in the Fiscal Year 1976 ERDA Budget, (Washington, D.C.: Government Printing Office, 1975) pp. 1-2.

[36] *Ibid.*, p. 2.

Few clear examples of technology assessment activities could be given on the basis of information contained in the budget request.

The OTA also raised several issues concerning ERDA's technology assessment activities, or lack thereof, as described in ERDA's Plan and Program. These issues will be explored after some background on what might be called the Agency's organization for technology assessment.

ORGANIZATION FOR TECHNOLOGY ASSESSMENT

ERDA's mission makes it the Federal Government's lead agency for research on health and environmental problems of energy systems. Until recently, the work in accordance with this responsibility appeared to have constituted virtually all of the activity within ERDA which might be regarded as technology assessment. Each of the ERDA program AA's is concerned with the health, safety, and environmental impact of the various activities within his area of responsibility. However, the Assistant Administrator for Environment and Safety (AAES) has the most far reaching responsibilities for technology assessment. It is his task to coordinate, oversee, and recommend changes in all of the Agency's activities in this area as well as to conduct, under his own supervision, R&D related to health, safety and the environment which is judged to be more appropriate as an Agency-wide effort. The AAES is also responsible for ensuring the compliance of all the Agency's programs with all laws and regulations governing health, safety and environmenatl protection (OHSA, EPA, etc.)[37]

OTA ANALYSIS

The OTA response to this arrangement fell primarily within two categories:

(1) ERDA has interpreted its mission for technology assessment too narrowly, and

(2) there is a danger that the results of ERDA's studies in technology assessment will not be adequately integrated with its technological developments.[38]

It should again be noted that the words "technology assessment" or similar terminology did not appear in any of the ERDA statements or documents encountered during this study. It was necessary to translate what appeared to be ERDA's technology assessment activities into this terminology.

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[37] U.S., Congress, Joint Committee on Atomic Energy, Subcommittee on Legislation, ERDA Authorizing Legislation - Fiscal Year 1976, Hearings, 94th Congress, 1st Sess., February 18 and 27, 1975 (Washington: Government Printing Office, 1975), pp. 114-1145.

[38] OTA Analysis of the ERDA Plan, *op. cit.*

The first category of OTA issues mentioned above is summarized by the statement:

> ERDA's program plans, budgetary commitments, and professional staffing do not give adequate attention to social, economic, environmental and behavioral research needs, even though the legislative record makes clear that ERDA is given responsibility beyond technological R,D&D.[39]

As a result of this statement, ERDA has begun to study social and institutional technological impacts, although this research still appears to be at a relatively low level. However, at least the recognition of these factors has occurred in a substantive way.

As for the second matter cited above, it was recognized by OTA that while the AAES had the responsibility for overseeing the environmental and health research activities of the entire Agency, there did not appear to be a strong enough link between the AAES and the technologically oriented divisions to ensure the proper integration of these concerns with technological developments.[40] This may or may not be true but OTA chose a poor example to illustrate the matter. Although the purpose of this paper is not to critique the OTA analysis, one point might facilitate putting ERDA's technology assessment activities into perspective. It appears that there was some difficulty in the differentiation between "environmental research" and "environmental control technology." The former is the identification and study of possible adverse environmental impacts of a given technology, i.e., technology assessment as defined here. The latter is the attempt to minimize the adverse impacts _which have already been identified_. This is a technology in itself. OTA pointed out that the ERDA Plan and Program placed most of the funding and manpower allocations for "controls technology development" under program AA's other than AAES, but that "the only substantive discussion of needs for environmental, health, social and institutional research is housed" in those sections of the report describing the AAES programs.[41] But there was not necessarily the conflict which was implied.

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[39] Ibid., p. 30.

[40] Ibid., p. 228.

In any case, during congressional testimony on the FY 77 budget, the AAES described the activities which had taken place in four environmental and safety programs: (1) Biomedical and Environmental Research (BER), (2) Environmental Control Technology (ECT), (3) Operational Safety (OS), and (4) Reactor Safety Facilities (RSF).[42]

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[41] _Ibid_.

[42] Statement of Dr. James L. Liverman, Assistant Administrator for Environment and Safety, ERDA, FY 1977 Appropriations Hearing, March 24, 1976 (unpublished)

The testimony covered all of the ERDA activities in these areas, not just those of the AAES. From the program descriptions, it was easy to identify the BER program as encompassing virtually all of ERDA's technology assessment activities.

Chapter 6

INSTITUTIONAL RELATIONSHIPS

The first priority of ERDA's involvement with institutions on the local, State and international level is the contribution of these relationships to the supply of energy sources to the United States. On the State and local levels, this appears to be the sole purpose of ERDA relationships. On the international level, ERDA inherited programs from the AEC which were designed for other purposes and these remain. U.S. energy related programs are now being developed, however. These relationships with local, State, and international institutions are discussed briefly in this chapter.

STATE AND LOCAL

The ERDA programs which exist or are being developed that involve State and local governments have the purposes of obtaining inputs to the ERDA Plan from these governments and helping to implement the Plan. The first of these was mentioned in Chapter 3. Also, ERDA has begun to sign memoranda of understanding with the States which provide "for the State to identify regional needs, skills and resources in energy-related areas and then submit specific proposed projects to ERDA for funding, technical advice or other support."[43] The States submit energy project proposals through Program Opportunity Notices (PON's). The PON's are reviewed by the concerned program AA and judged for their merit as a contribution to ERDA's overall national energy plan. The Assistant Director for State and Local Relations, ISL "plans and directs a program of direct liaison with State and local governments, and regional officials that informs and assists in the R&D energy activities of government at those levels."[44]

INTERNATIONAL

The AEC had a long history of international cooperation in the peaceful uses of atomic energy as well as other activities in the national security field. With the advent of ERDA's broader mission, these relationships on the international level have expanded into other areas. Through the Office of International Affairs, ERDA is exploring potential cooperative efforts in energy R&D with other nations through its participation in the activities of the new International Energy Agency.

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[43] Information from ERDA, week ending March 24, 1976, p. 1.

[44] From organizational chart of Assistant Director for State and Local Relations.

As with ERDA-State and local cooperative efforts, the primary criterion for approval of such projects by ERDA is the degree to which they will complement ERDA's national energy plan.[45]

This is in contrast to the goals of the Atoms for Peace Program which was initiated during the mid-1950's when the U.S. could expect slight reciprocal benefits towards satisfying its own energy needs, at least during the short term. This of course was during a period when such matters were perceived as far less urgent. The legacy of this program has increasingly reaped returns as other countries have built up their capabilities in the energy field, particularly those industrialized nations of Western Europe and Japan. For instance, under a new agreement, West Germany and the U.S. have begun to exchange energy R&D reports. The reports from West Germany will become part of ERDA's bibliographic base. A similar arrangement may be forthcoming between the U.S. and the Scandinavian countries, the United Kingdom, France, and Japan.[46]

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[45] ERDA News, March 19, 1976, p. 4.

[46] Ibid., p. 2.

CONCLUSION

The primary challenge facing ERDA in the near term will be the task of reorienting the activities of its inherited component parts toward meeting a new, high priority mission. Balance will need to be maintained between the continuation of old programs and the undertaking of the new, without sacrificing the efficiency and proper timing of either. Objectivity will be required in decisions to assign non-nuclear or non-technical programs to field organizations which have in the past developed expertise primarily in the nuclear energy field. The balance of emphasis on nuclear vs. non-nuclear programs will continue to be questioned.

There is ample evidence that ERDA has been making a concentrated effort to rectify the "shortcomings" in the present organization which have been pointed out in critiques from a variety of sources. To be sure, this has been a result of the highly visible position in which ERDA finds itself. On the other hand, ERDA will need to surmount attempts to politicize its activities by both the Congress and the Executive. If these tasks can be accomplished before bureaucratic inertia and old age set in, ERDA will be well on the way to accomplishing its long range goals.

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THE NATIONAL INSTITUTES OF HEALTH, PATRON OF BIOMEDICAL SCIENCE

by

George B. Riley

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Preface

The National Institutes of Health located in suburban Bethesda, Maryland, on 306 acres of well manicured lawns shaded by majestic old trees, through which modern office buildings and laboratories reach skyward, is probably one of the most important centers of biomedical research and its administration in the world. In the triad formed of NIH, the National Naval Medical Center and the National Library of Medicine, there is a quiet, well-landscaped nook in which stands a "Tree of Hippocrates" with appropriate identifying tablet. This entire milieu is appropriately symbolic of the professionalism and tasteful dedication of The National Institutes of Health to the conduct and support of biomedical research excellence.

Of great significance in actuality, as reflected in this presentation, NIH is not a monolithic single, rigid organization, but rather a family of autonomous entities, each pursuing its own mandate and interests with a minimum of conflict with siblings. The very diversity of the organizational structure presents both challenge and unique opportunity to study on somewhat less than a global basis the plurality of our biomedical needs and interests, but also the multiplicity of factors and interactions (legislative, executive, special interest groups, etc.) involved in the management and conduct of a Federally funded program to improve biomedical knowledge and quality of medical care available to the American people.

Studies and investigations required for the collection, coordination and in some cases interpretation of material to be synthesized into this presentation were most stimulating. They offered the opportunity to put into one (hopefully coherent) presentation, years of experience as a scientist administrator of the many grant supported programs, with information and insight into the multiple facets which make up this unique agency. Just as one may overlook the framework and foundation of a house when overly intent on the installation of kitchen cabinets, this presentation has offered the opportunity to "get out of the kitchen," enjoy the function and beauty of each of the structural components and appreciate the magnificance and grandeur of the total architectural edifice.

A study of the evolution and continuing growth and change of NIH from its inception as one of the first federal agencies offers a microcosmic reflection of the evolution, growth, needs, and responsive change of the United States as a country of pluralistic ethnicity, political and religious persuasions. Just as the perceived needs of the people have led to modifications and legislation to attempt the satisfaction of these needs, the character and emphasis of activities have been modified or intensified to serve the biomedical needs of the Nation. It is hoped that efforts of information coordination and narration will serve to clarify and document the role of the National Institutes of Health as the Patron of Biomedical Science.

PERSONS INTERVIEWED FOR PREPARTAION OF THIS PAPER

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Dr. Donald T. Chalkley, Director, Office for Protection from Research Risks, N.I.H.

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Working associates within the National Heart and Lung Institute not listed as interviewees because of frequent contact and familiarity with their programs and activities.

Historical Background

The organizational unit currently identified as the National Institutes of Health, Department of Health, Education and Welfare within the Executive Branch of the U.S. Federal Government has enjoyed a number of distinctions during its evolution. One of the most innovative of these distinctions is the development and utilization of a "peer review system" to determine the recipients of grants of federal funds totaling billions of dollars and constituting the greatest source of biomedical research support in the United States. Significant milestones in the development are of interest and are presented chronologically.

1798 - The Marine Hospital Service - Progenitor of NIH was established with the signing by President John Adams of an act for the relief of sick and disabled seamen on July 16.

1878 - The first Federal Quarantine Act was passed April 29. Congress appropriated funds "for investigating the origin and causes of epidemic diseases, especially yellow fever and cholera," December 21.

1879 - The National Board of Health was created by law on March 3. It represented the first organized, comprehensive, national medical research effort of the Federal Government.

1912 - The Marine Hospital Service and its successor The Public Health and Marine Hospital Service was changed to Public Health Service on August 14 by the Public Health Service Act which authorized this agency to investigate the diseases of man and the pollution of navigable waters, signed by President Taft on August 14.

1918 - The Chamberlain-Kahn Act, passed July 9 provided for the study of veneral disease. The Public Health Service made grants to 25 institutions, establishing a precedent for the Federal Government to seek assistance of scientists through grants.

1930 - Under Public Law 71-106 passed April 9, the Advisory Board for the Biologics Control Division became the National Advisory Health Council. On May 26 the Ransdell Act redesignated the Hygienic Laboratory as the National Institute of Health.

1937 - With the reorganization of the National Institute of Health into eight divisions, the biologics control program, previously the responsibility of the Division of Pathology and Bacteriology, NIH, was assigned to a newly established Division of Biologics Control (redesignated Biologics Control Laboratory, 1944).

Congress authorized the National Cancer Institute on July 23. The bill was introduced in the Senate under the names of all 96 Senators.

1938 - The National Advisory Cancer Council recommended approval of the first awards for fellowships in cancer research on January 3.

Congress authorized construction of new, larger laboratory facilities and NIH moved to Bethesda, Maryland in July.

1943 - The Public Health Service Act was approved on July 1, consolidating and revising existing public health legislation, and giving NIH the legislative basis for its postwar program with general authority to conduct (biomedical) research.

1946 - The Research Grants Office was created at NIH in January to administer the Office of Scientific Research and Development projects transferred to the Public Health Service at the end of World War II, and to operate a program of extramural research grants and fellowship awards.

1950 - Dr. William H. Sebrell Jr. was appointed Director of the National Institutes of Health on October 1.

1953 - The Public Health Service became part of the newly created Department of Health, Education, and Welfare on April 11.

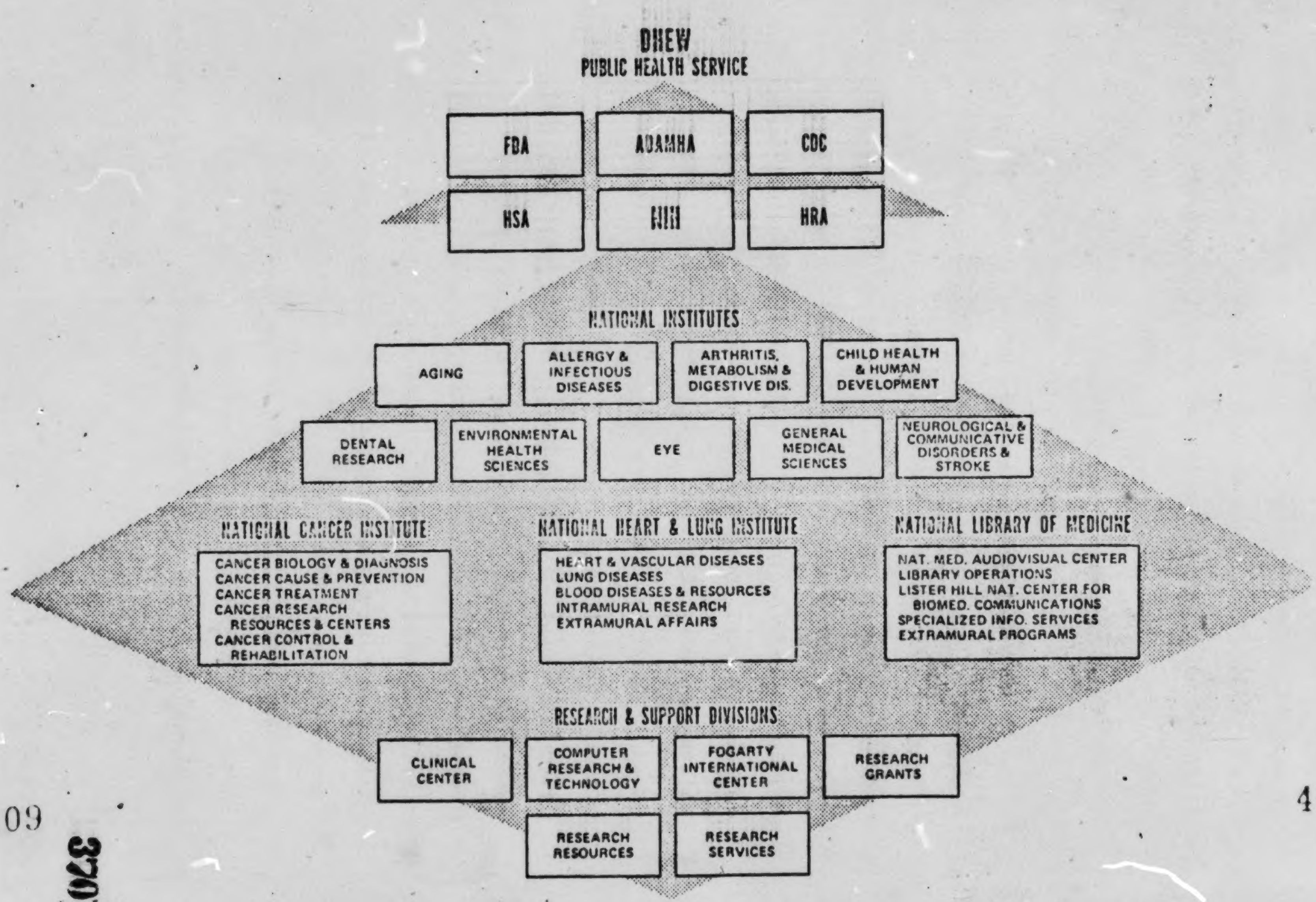
1955 - James A. Shannon, M.D., Ph.D., an outstanding biomedical scientist in his own right, was appointed Director of the National Institutes of Health on August 1. Serving in this capacity until 1968 when his successor Dr. Robert Q. Marston was sworn in, Dr. Shannon, through his dynamic leadership and "creative administration" became a dominant figure in the growth and contributions of biomedical research and established NIH as the leading agency in support of the entire scope of Biomedical Science.

As exemplified by the above chronology of events, the National Institutes of Health as currently recognized has proceeded through a rather circuitous evolutionary process of growth (accompanied by significant change in personnel, personality and purpose) since its inception as the first federally supported biomedical research agency. Usually legislation was inacted for such changes, the chronology of which is provided in Appendix A. As of any evolutionary process, all structures are transient, with change in relationships and modification of function continuous. Although everchanging, it can safely be observed that from a meager hospital-laboratory infancy, NIH has grown to full adulthood in the family of Federal agencies as the prime patron of Biomedical Science.

Organizational Structure and Functions

For the sake of at least momentary accuracy it is of some value to describe and attempt to understand the organizational structure of the Department of Health, Education, and Welfare as currently constituted within which the National Institutes of Health resides. The fact that the National Institute of Mental Health, originally a member of NIH, has metamorphosed into the Alcohol, Drug Abuse, and Mental Health Administration, an agency of equal organizational standing with NIH, will not be belabored. As one of the six constituent agencies of the Department of Health, Education, and Welfare, the National Institutes of Health itself is subdivided into a number of bureaus, institutes, and divisions as shown on the chart following this page.

Categorical institutes have been established to satisfy the perceived or expressed need of particular constituencies or organ-disease syndrome oriented studies. These institutes are:


DHEW
PUBLIC HEALTH SERVICE
FDA
ADAMHA
CDC
HSA
NIH
HRA
NATIONAL INSTITUTES
AGING
ALLERGY & INFECTIOUS DISEASES
ARTHRITIS, METABOLISM & DIGESTIVE DIS.
CHILD HEALTH & HUMAN DEVELOPMENT
DENTAL RESEARCH
ENVIRONMENTAL HEALTH SCIENCES
EYE
GENERAL MEDICAL SCIENCES
NEUROLOGICAL & COMMUNICATIVE DISORDERS & STROKE
NATIONAL CANCER INSTITUTE
CANCER BIOLOGY & DIAGNOSIS
CANCER CAUSE & PREVENTION
CANCER TREATMENT
CANCER RESEARCH RESOURCES & CENTERS
CANCER CONTROL & REHABILITATION
NATIONAL HEART & LUNG INSTITUTE
HEART & VASCULAR DISEASES
LUNG DISEASES
BLOOD DISEASES & RESOURCES
INTRAMURAL RESEARCH
EXTRAMURAL AFFAIRS
NATIONAL LIBRARY OF MEDICINE
NAT. MED. AUDIOVISUAL CENTER
LIBRARY OPERATIONS
LISTER HILL NAT. CENTER FOR BIOMED. COMMUNICATIONS
SPECIALIZED INFO. SERVICES
EXTRAMURAL PROGRAMS
RESEARCH & SUPPORT DIVISIONS
CLINICAL CENTER
COMPUTER RESEARCH & TECHNOLOGY
FOGARTY INTERNATIONAL CENTER
RESEARCH GRANTS
RESEARCH RESOURCES
RESEARCH SERVICES

1. National Institute on Aging
2. National Institute of Allergy and Infectious Diseases
3. National Institute of Arthritis, Metabolic and Digestive Diseases
4. National Institute of Child Health and Human Development
5. National Institute of Dental Research
6. National Institute of Environmental Health Sciences
7. National Eye Institute
8. National Institute of General Medical Sciences
9. National Institute of Neurological and Communicative Disorders and Stroke

Other prestigious members of this organizational array which have by dent of the magnitude, scope, or importance of their efforts attained Bureau status:

1. National Cancer Institute
2. National Heart, Lung and Blood Institute (Legislation 1976)
3. National Library of Medicine

Clearly defined research and support divisions serving virtually all, but subservient to none of the above institutes and bureaus are:

1. The Clinical Center
2. Division of Computer Research and Technology
3. The Fogarty International Center
4. Division of Research Grants
5. Division of Research Resources

6. Division of Research Services

Closely affiliated with and interacting with NIH programs and sharing facilities on the NIH "campus" are:

1. The Bureau of Health Manpower -- A bureau of the Health Resources Administration
2. The Bureau of Biologics -- A bureau of the Food and Drug Administration
3. The National Institute of Mental Health -- A component of the Alcohol, Drug Abuse, and Mental Health Administration

This conglomerate (in the industry sense) of organizational entities subserves all the perceived or stated needs of biomedical research yet conceived and authorized by legislation. A detailed description of each organizational unit, its purpose, function and areas of interest is beyond the scope of this paper but is briefly summarized in Appendix B.

NIH Support of Biomedical Science

The scope, intimacy and ubiquity of the involvement of NIH in the support of training, research and virtually every conceivable activity contributing to the growth, aggrandizement and achievement of Biomedical Science not only taxes the imagination but indeed boggles the mind. The claim that this organization is the prime patron of biomedical science has not been challenged since World War II and is not likely to be questioned in the foreseeable future. Not only has the pursuit of biomedical research within its own laboratories been a foremost concern and has contributed significantly to biomedical knowledge but upward of 85% of funds budgeted to NIH has been channeled into the extramural programs which support research, training, and related activities for the betterment of biomedical science through contracts and grants to predominately non-governmental, non-profit organizations and institutions. At least 125 different funding mechanisms, the diversity and descriptions of which are shown in Appendix C, have been developed to facilitate the nurture of every conceivable aspect of biomedical science from predoctoral training (in every discipline even remotely related to biomedical science) through research projects, super projects (program projects), special centers of research, comprehensive centers, research resource support, and even formula grants (general research support) to institutions for virtually discretionary use in the support of studies by promising neophyte investigations.

The more or less self-explanatory charts which follow (Fig. 1-12) should help to elucidate the extent, kind, and impact of the NIH input into biomedical research and development during the past 10 to 20 years (1955-1975).

Fig. 1. National Health R & D, 1965 and 1975 As a Proportion of Total Health Costs and Total R & D Costs

The more than three-fold increase in total health costs during the ten years 1965 to 1975 undoubtedly reflects the strong influence of inflation on health care costs, particularly hospital and nursing home care which rose not only in total dollars but also in the percentage of health cost represented by such changes. Even though health related research and development costs increased slightly more than two-fold, the percentage of total health costs expended on research and development of new instrumentation and care modalities decreased significantly (20%) during this period. However, total research and development for all sectors increased by a factor of only 74% from $20.1 billion to $35.0 billion from 1965 to 1975. Expenditures for health related research and development increased by a factor of 2.47 during this period ($1.9 to $4.7 billion) and the percentage of total R & D attributable to health increased by approximately 50%. As will be seen in subsequent figures, the costs for biomedical research and development are borne by a variety of organizational entities.

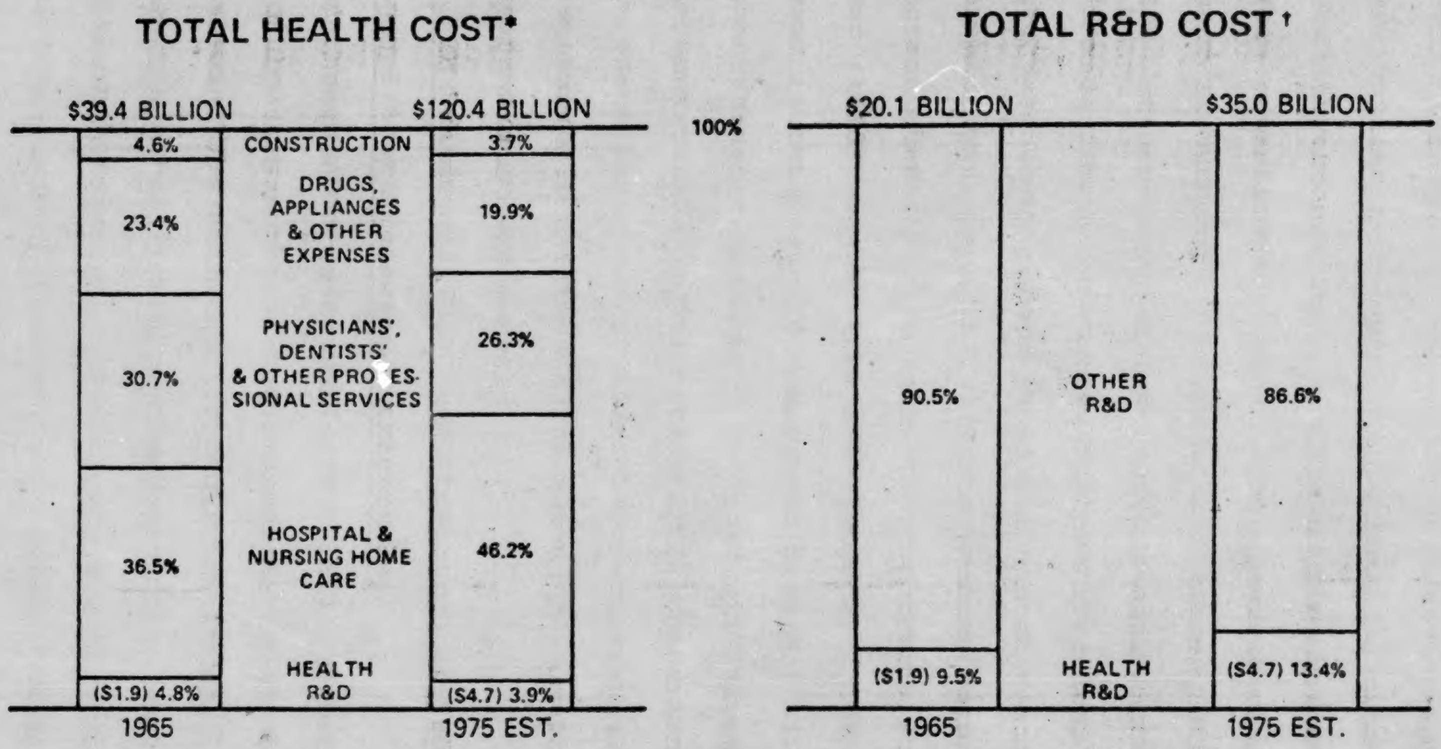
Fig. 2 National Support for Health R & D by Source and Performer, 1974

Health related research and development is conducted primarily in laboratories of federal agencies, state agencies, industry, institutions of higher education, other nonprofit organizations, and in foreign laboratories. Of the total contributed from all sources ($4.452 billion) 39% or $1.740 billion is spent in institutions of higher education. A significant amount (28%) is also spent in the laboratories, primarily of the pharmaceutical industry. Interestingly, enough, the amount contributed by all the states to health research and development is only slightly (25%) greater than the contributions from private non-profit organizations or individuals. As would be expected, the bulk of research and development support for institutions of higher learning derives from federal, state, and private non-profit funds, with only token input from industry.

Fig. 3 NIH R & D Funds as a Proportion of Nation's Health R & D Support, 1965 - 1975 Est.

With a more than two-fold increase in total expenditures for health related research and development during the years 1965-1975, the proportional contribution to these costs from different sources has remained fairly constant. With minor annual fluctuations, there has been a 4% decrease in contributions from "other" (mostly non-profit organizations, foundations, and individuals) sources which has been more than offset by a 5% increase in the funding derived from industry. During this period all federal sources of support for health R & D has been fairly stable at 60-61% of the total with NIH consistently accounting for 60% to 65% of all federal support of such activities. Since the initiation of the grant and contract support

Figure 1
NATIONAL HEALTH R&D, 1965 AND 1975, AS A PROPORTION OF . . .



n Social Security Administration, with adjustments of R&D and therefore of totals, to conform with NIH data. †From NSF and NIH.

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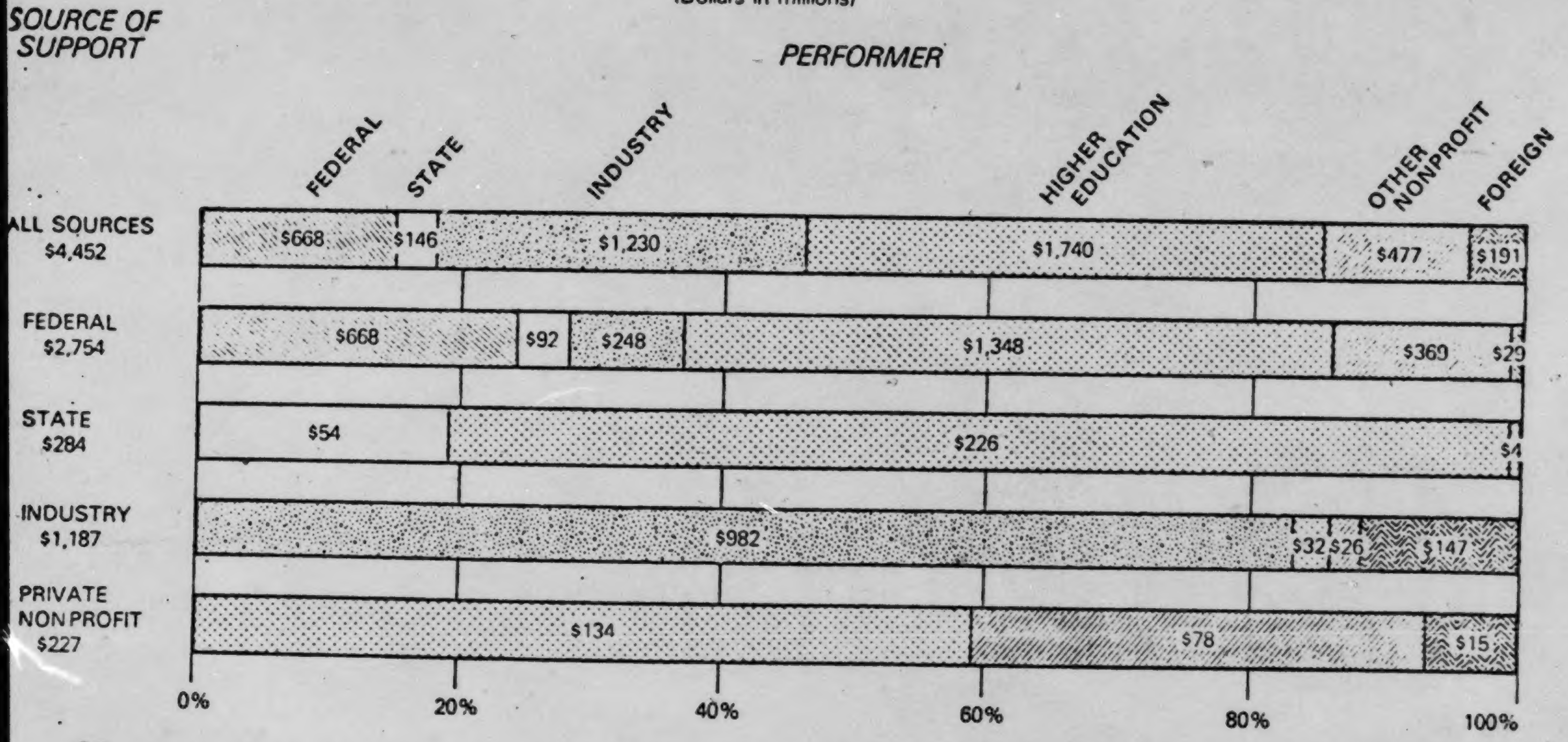
Figure 2

NATIONAL SUPPORT FOR HEALTH R&D BY SOURCE AND PERFORMER, 1974

(Dollars in millions)



of biomedical science effort by NIH it has rapidly increased in magnitude so that for more than the last ten years, the National Institutes of Health through its multifarious programs has firmly established itself as the greatest single source of support for biomedical science in the U.S. With the continual dramatic annual increase of monies from all sources for health related research and development over the last ten years, the chilling impact of inflation becomes painfully apparent when it is realized that in terms of constant (1965) values there has been only a 50% increase in the level of support of health R & D rather than the apparent 2.44 factorial increment in expenditures. Quite obviously, the constantly increased infusion of dollars has not resulted in comparable alleviation of the needs for health research and development.

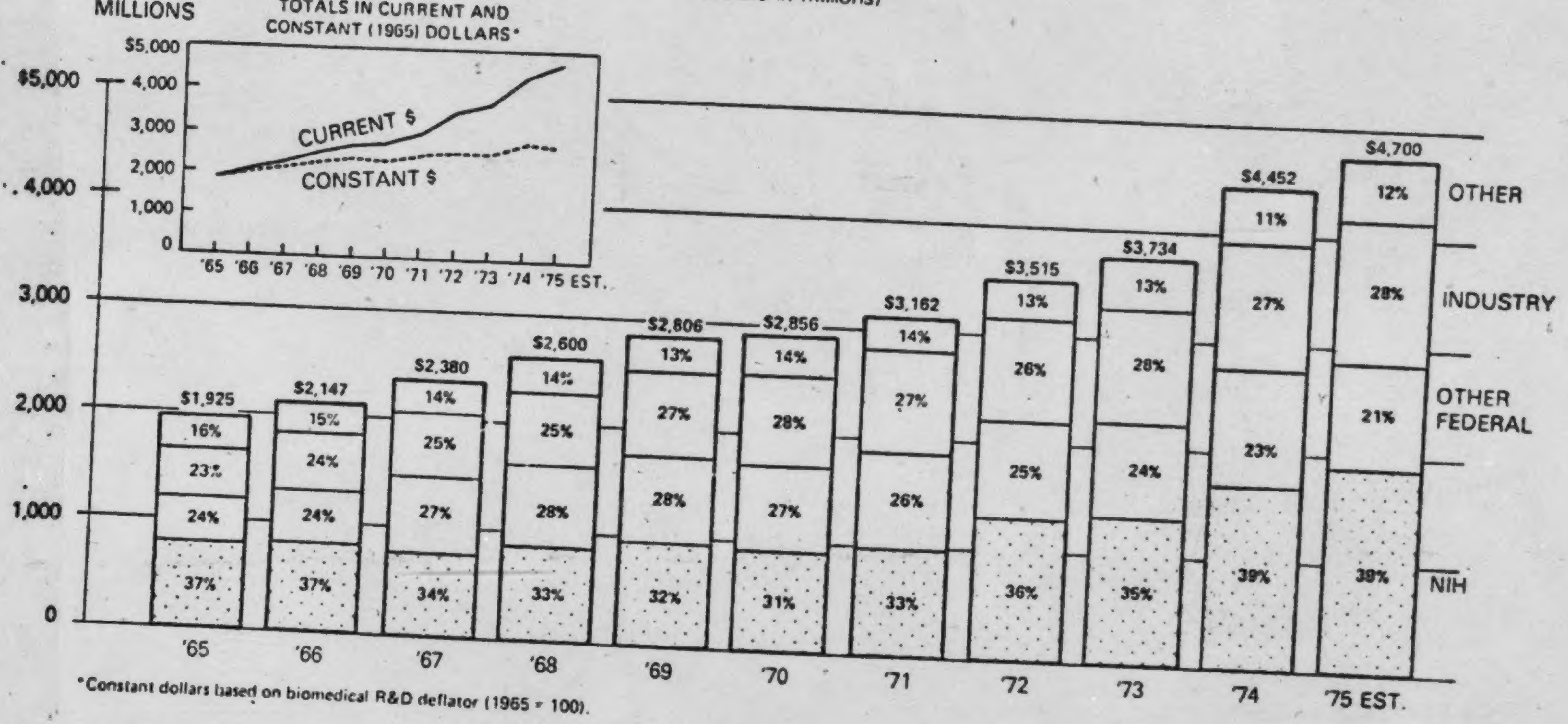
Fig. 4. NIH Funding of R & D and Proportion of Federally Supported R & D at Academic Institutions

Even though NIH funded only 10% of all federally supported research and development in 1974 which totalled $17.4 billion, its contribution was 3 1/2 times that of all other components of the Department of Health, Education, and Welfare as well as 3 1/3 times the input of the National Science Foundation. The impact of NIH on biomedical research and devel-

Figure 3

NIH R&D FUNDS AS A PROPORTION OF NATION'S HEALTH R&D SUPPORT, 1965—1975 EST.

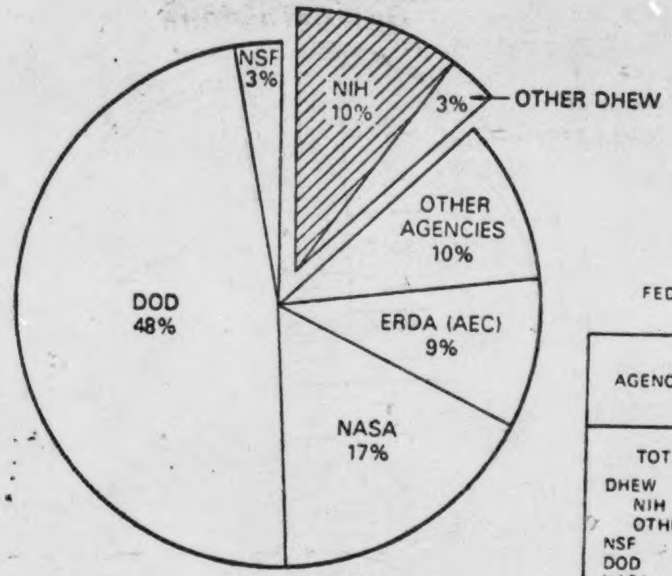
(Dollars in millions)



*Constant dollars based on biomedical R&D deflator (1965 = 100).

Figure 4
NIH IN FISCAL YEAR 1974 FUNDED. . .

10% OF ALL FEDERALLY SUPPORTED R&D



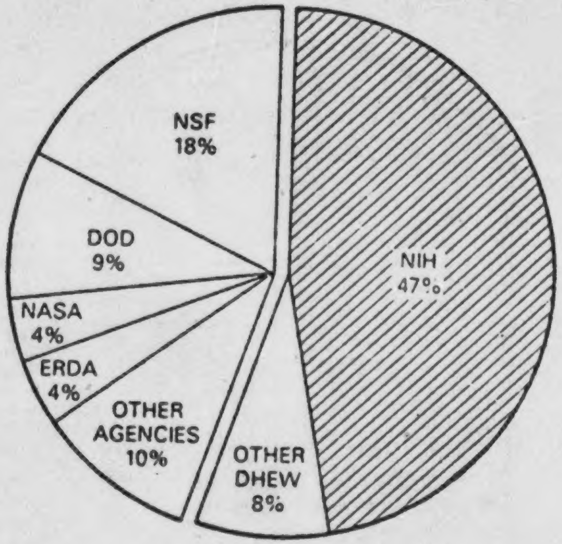
$17.4 BILLION

SOURCES: *NSF and NIH.*

FEDERAL SUPPORT, FY 1974
(IN MILLIONS)

AGENCY	ALL FED. R&D	R&D AT ACAD. INST.
TOTAL	$17,438	$2,215
DHEW	2,290	1,208
NIH	1,737	1,027
OTHER	553	181
NSF	556	389
DOD	8,420	198
NASA	3,002	99
ERDA	1,489	94
OTHER	1,680	227

47% OF FEDERALLY SUPPORTED R&D AT ACADEMIC INSTITUTIONS



$2.2 BILLION

opment becomes clearly defined when it is recognized that expenditures by other agencies such as DOD, NASA, and ERDA are predominantly for non-health related efforts whereas NIH has *no* activities not related to biomedical science. Another dramatic exemplification of this contribution is seen in the fact that during 1974, of the $2.2 billion of federally supported research and development (in all fields) at academic institutions (including basic science and non-medical facilities) 47% was derived from the National Institutes of Health. Clearly, survival of academia as currently constituted would be most precarious, if not impossible, without the patronage of this federal agency.

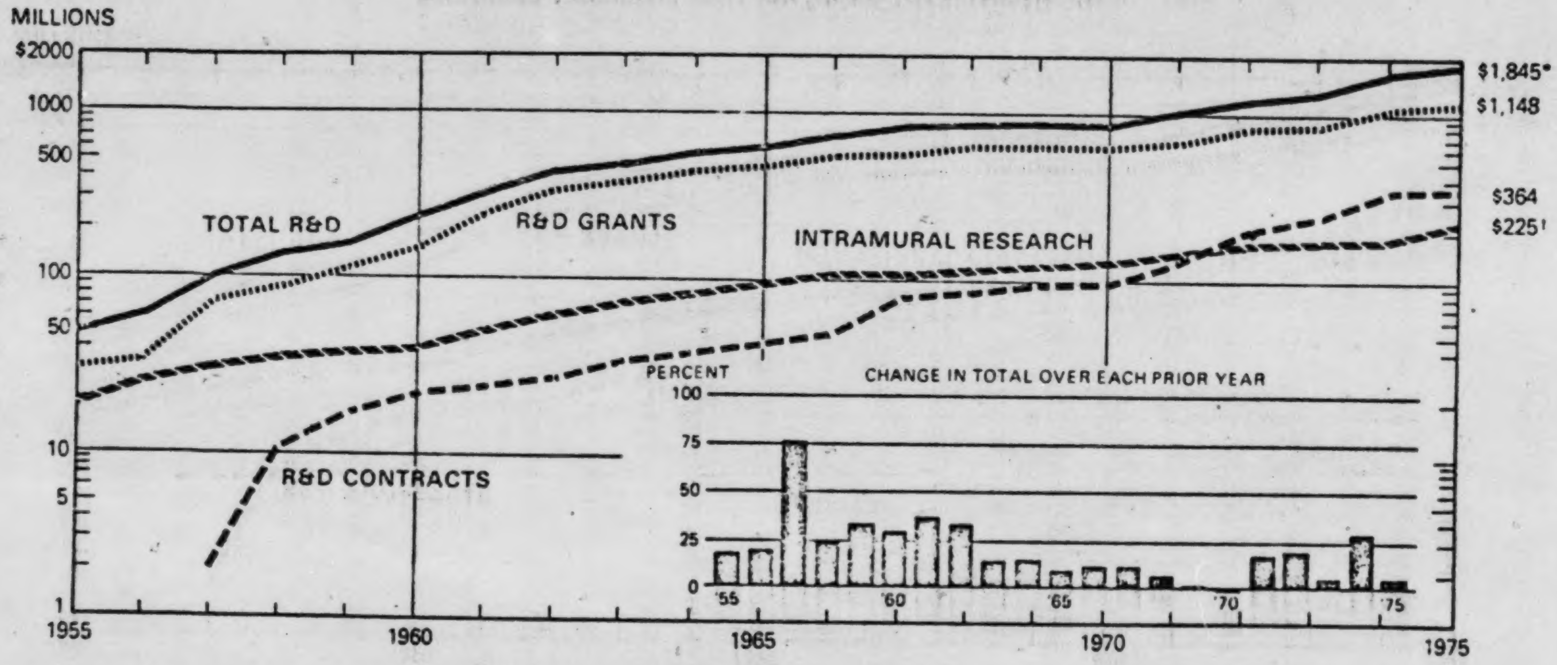
Fig. 5 NIH Funds Obligated for R & D, Fiscal Years 1955-1975

As will be discussed in a separate section on the (intramural) research conducted within the laboratory facilities of NIH such efforts have burgeoned from a level of less than 20 million dollars in 1955 to approximately $225 million in 1975. However, even this, not inconsequential, sum represents only 12% of NIH expenditures ($1.845 billion) for research and development in 1975. The remaining $1.620 billion is channeled into the (extramural) programs for the conduct of training and investigations in non-federal institutions. Such efforts encompass a plethora of program types alluded to previously and described

Figure 5

NIH FUNDS OBLIGATED FOR R&D, FISCAL YEARS 1955–1975

EXCLUDING PROGRAMS THAT HAVE BEEN TRANSFERRED OUT



[*] Includes R&D as shown in Table 7 + Foreign Currency Program ($542 thousand in FY 1975) + portions of Cancer Control, Management & Services, and NLM.

[†] Includes Laboratory & Clinical Research, Biometry Epidemiology Field Studies, Collaborative Research & Support, and FIC.

in Appendix C.

Although these programs are supported predominantly by the grant mechanism, there has been a steady increase in contract support from less than one million dollars in 1957 to approximately $364 million in 1975. Contracts are limited to mission oriented research and targeted development, whereas grants are utilized for an almost limitless range of efforts. A more detailed discussion of these two support mechanisms is presented in a later section of this paper. The vicissitudes of federal funding predicated on the whimsy and fickle favor of legislative support is vividly demonstrated in the dramatic incremental increase of NIH funding of R and D from 1955 to 1970, in which year the level of support fell below that of the previous (1969) year which itself did not enjoy an increase equal to inflation of costs. It is quite clear that the hey day of growth for NIH was 1955-1965, the era of Fogarty, Hill, Lasker and Shannon. Within recent years there has been a slight resurrection reflecting inflationary pressures and increasing attention to activities of the Cancer and Heart and Lung Institutes.

Fig. 6 NIH Awards for R & D and their Percentage Distribution, Fiscal Years 1967-1975

During the period 1967-1975 there has existed an ever-changing relationship in the number of activities supported under different programs and mechanisms. Whereas the single research project grant was the prototype for NIH support of biomedical science and constituted the overwhelming majority of support for such activities, this domain has steadily been infiltrated by program project and center grants as well as R & D contracts, resulting in a constantly decreasing percentage of support going to the single project-investigator initiated research grant. Growth of R & D contracts has paralleled or, in some cases, exceeded the decrease in research grants support. The magnitude of the above change in so short (8 years) a period is dramatic evidence of response to legislative mandate for directed or targeted research for "predictable payoff" at the expense of individual investigator initiative and license to pursue esoteric investigations whose most immediate contribution might be intellectual stimulation.

Fig. 7 Percentage Distribution of NIH Awards for R & D by NIH Component, Fiscal Years 1967 and 1975

Diversity of interests and activities among the various institutes and divisions at NIH is reflected in the funding mechanisms employed by these components. For example, the Division of

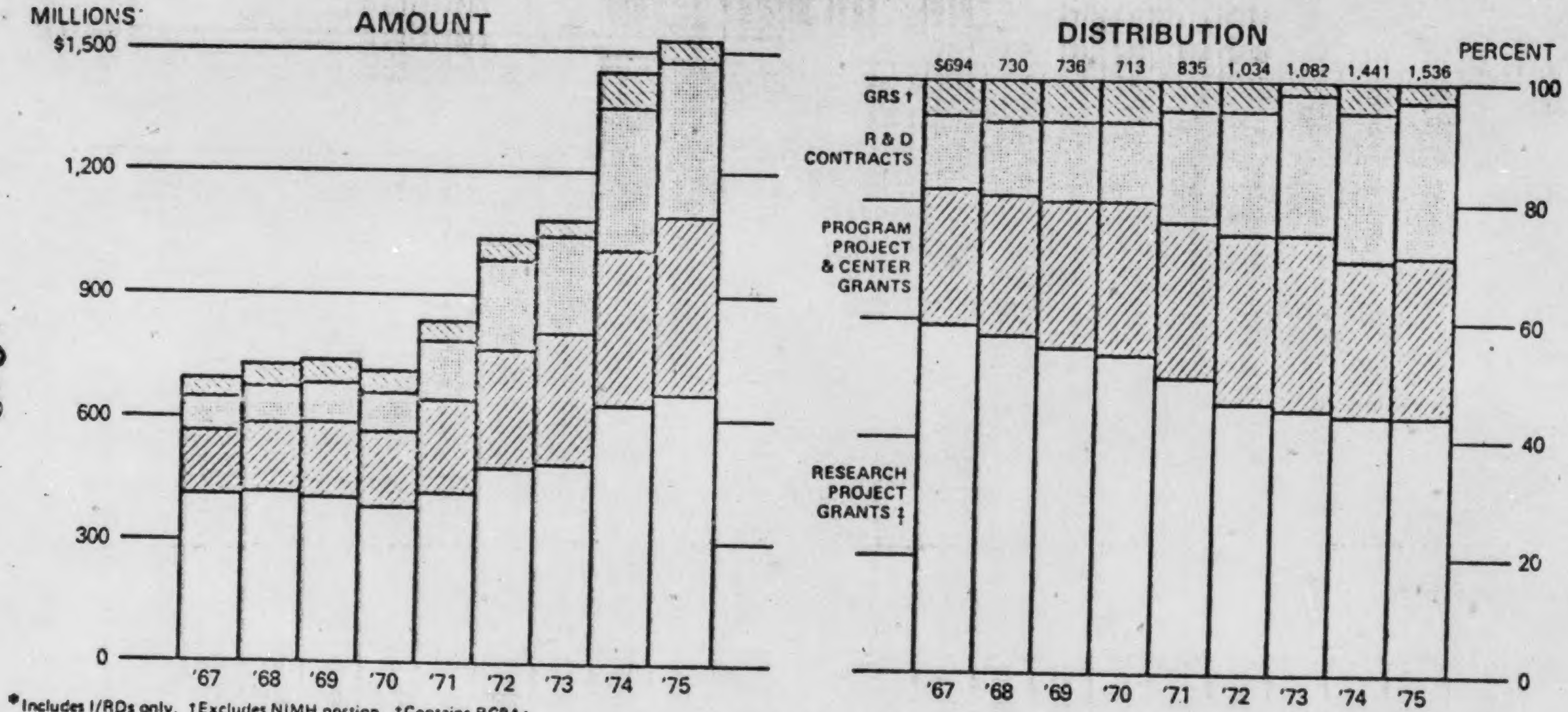
Research Resources has very few research project grants and only slightly more R & D contracts. However, program projects and centers comprise perhaps 50% of its research and development budget and all general research support grants from NIH are made by this division. None of the institutes fund general research support grants and the percentage of funds applied to other support mechanisms varies widely between institutes. Visual perusal of Fig. 7 presents graphically a more accurate conception of variations, implication, and interpretations than would be possible by excessive discourse and verbage.

Fig. 8 Percentage Distribution of NIH Research Grants by NIH Component and by Performer, Fiscal Years 1969 and 1975

Support by whatever mechanism from NIH is directed almost exclusively to non-profit organizations with between 80% and 90% going to medical schools and other components of higher education. When hospitals are added to this list, the only remaining significant recipients of NIH largesse are various research institutes which may be autonomous or affiliated with institutions of higher education. Examples of such institutes are Battelle Research Institute, Jet Propulsion Laboratories, Stanford Research Institute and others. Variations of percentages of support

Figure 6

NIH AWARDS FOR R&D AND THEIR PERCENTAGE DISTRIBUTION FISCAL YEARS 1967 – 1975*

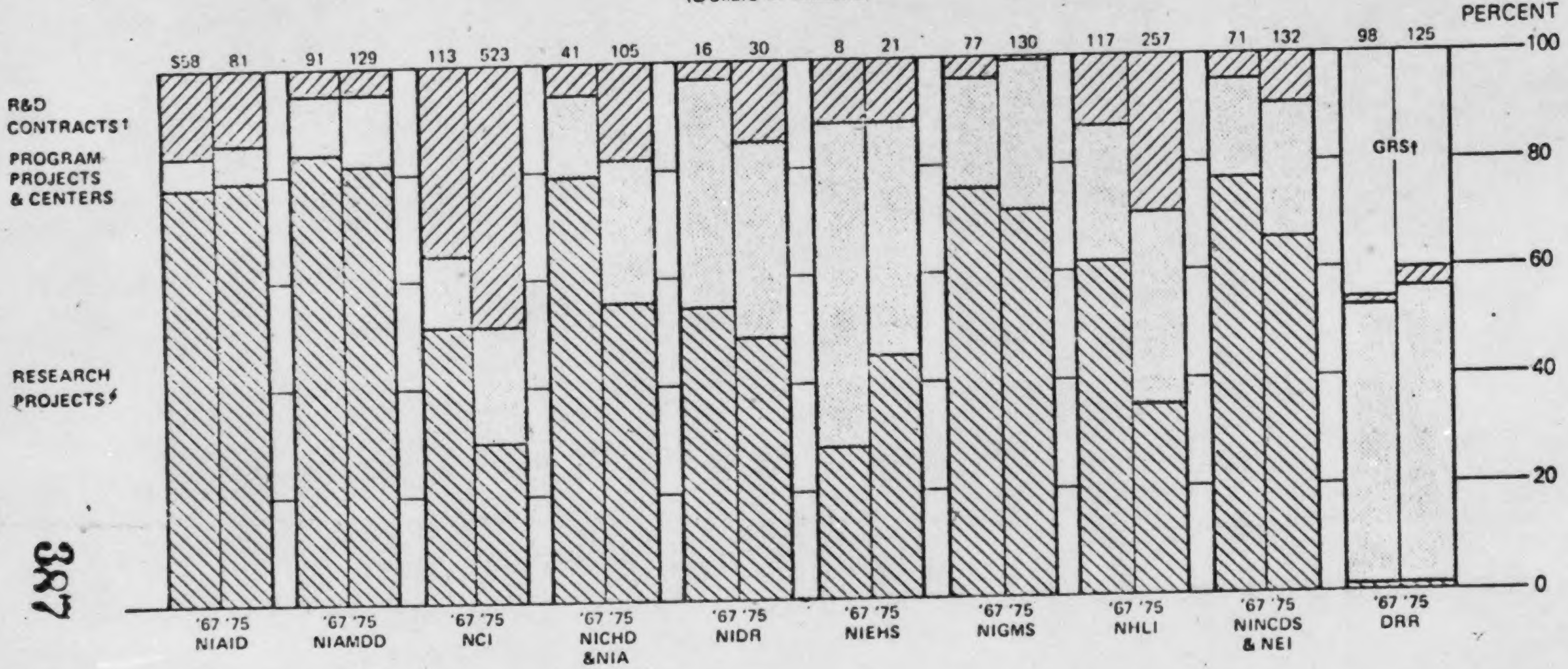


*Includes I/RDs only. †Excludes NIMH portion. ‡Contains RCPAs.

Figure 7

PERCENTAGE DISTRIBUTION OF NIH AWARDS FOR R&D BY NIH COMPONENT, FISCAL YEARS 1967 AND 1975*

(Dollars in millions)

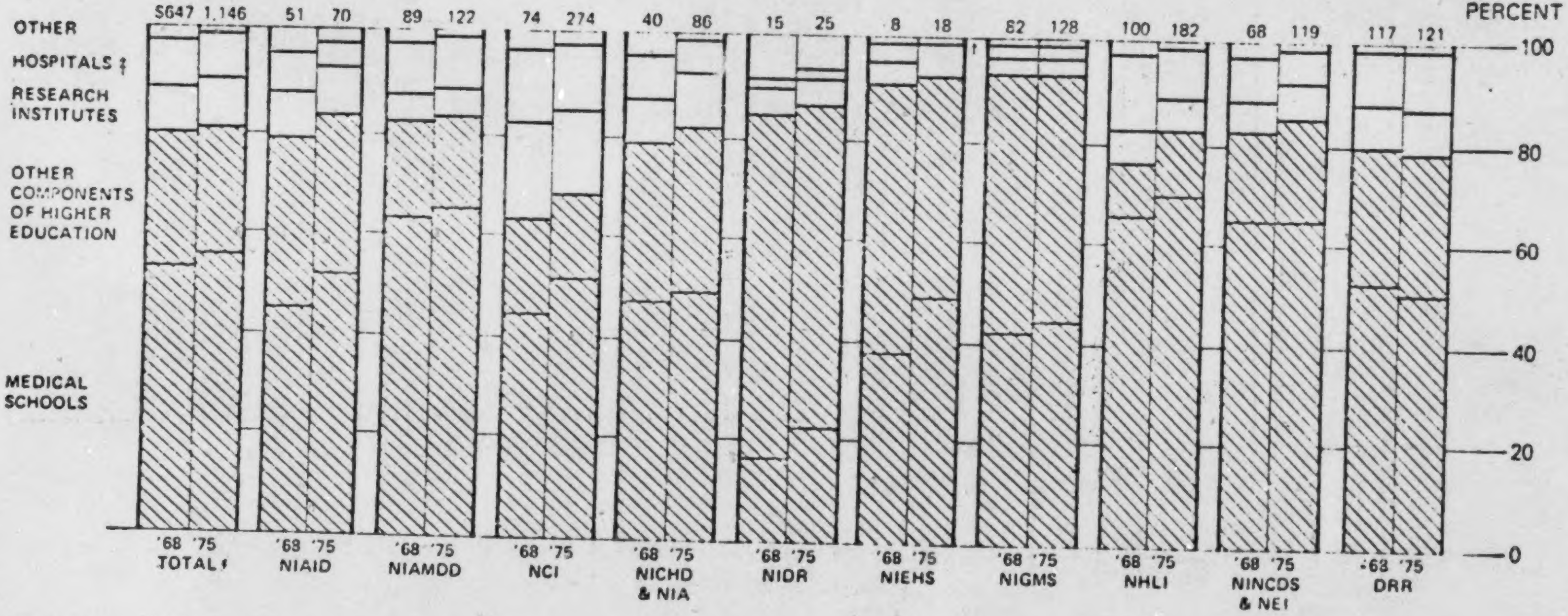


*Includes I/RDs only. †Excludes contracts for CC, DCRT, DRG, DRS, OD, and joint. ‡Excludes NIMH portion. §Contains RCPAs.

Figure 8

PERCENTAGE DISTRIBUTION OF NIH RESEARCH GRANTS BY NIH COMPONENT AND BY PERFORMER, FISCAL YEARS 1968 AND 1975 *

(Dollars in millions)



*Includes I/RDs only. Contains RCPAs. †Contains no Other. ‡All hospitals except those owned by institutions of higher education or research institutes. §Contains FIC in 1968 going to different recipients from the various components of NIH clearly reflects the differences in their categorical interests. For example, the significant funding to hospitals from NCI and NHLI clearly demonstrates their interest in clinical research, whereas NIDR and NIGMS have little activity or funding in this area. The significant contribution to hospitals from DRR represents provision of funds for construction of medical research facilities rather than the direct support of investigational projects _per se_. It should also be noted that some NCI funding is for construction, an authority not enjoyed by other institutes. See Appendix A - Legislative Chronology.

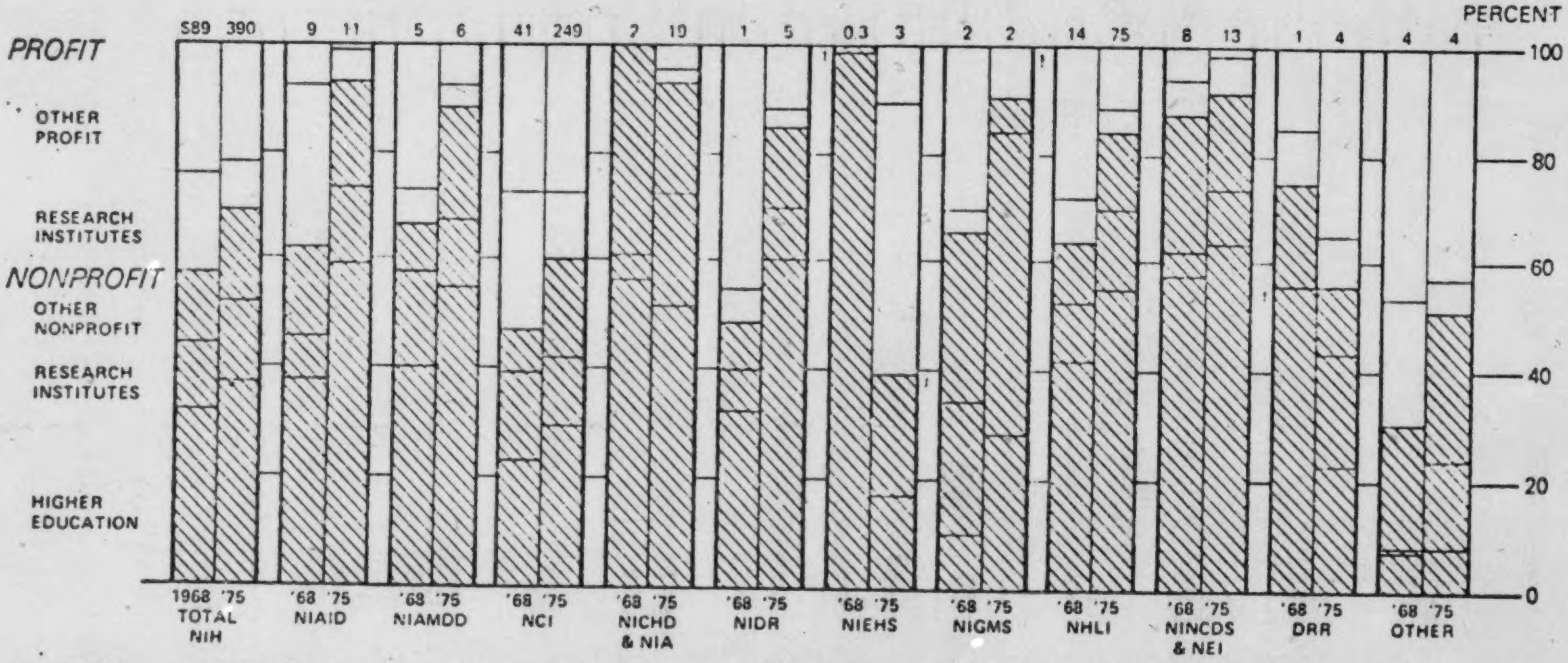
Fig. 9 Percentage Distribution of NIH R & D Contracts by NIH Component and by Performer, Fiscal Years 1968 and 1975

A dramatic increase in research and development funded via the contract mechanism by NIH has occurred in the recent past; from $89 million in 1968 to $390 million in 1975. Contracts are awarded to profit making as well as non-profit organizations for performance of specified activities closely adhering to protocols developed by NIH staff (usually with the assistance of outside consultants) and under rather strict surveillance of this staff for the achievement of specific or targeted ob-

Figure 9

PERCENTAGE DISTRIBUTION OF NIH R&D CONTRACTS BY NIH COMPONENT AND BY PERFORMER, FISCAL YEARS 1968 AND 1975 *

(Dollars in millions)



*Includes I RDs only. †Contains no Research Institutes. ‡Contains no Other Profit. §Contains no Other Nonprofit. ‖Includes CC, DCRT, DRG, DRS, OD, and joint.

jectives. Of all the institutes shown, the only one that has not increased its contract program between 1968 and 1975 is the National Institute of General Medical Sciences, the generality of whose mandate minimizes the need or desirability of directed and/or targeted investigations. Of all NIH, it is within the scope of NIGMS that the universality of biomedical sciences is most effectively demonstrated. Of interest is the fact that in 1968 NICHD and NIEHS awarded contracts only to non-profit institutions, whereas other institutes gave at least token contract awards to profit making organizations. By 1975 even these two holdouts had capitulated and made awards to profit makers, thus deserting the last bastions of scientific altruism and acknowledging the de facto commercial invasion of biomedical science. Although NCI has increased R & D contracts from $41 million to $249 million (a factor of 6.07) between 1968 and 1975, other institutes such as NICHD, NIA, and NIEHS have increased their contracts by a factor of almost 10 during the same period. However, the dollar amounts are of a lower order of magnitude. Organizations placed in the "other" category represent service or supportive groups distinct from the categorical institutes.

Fig. 10 NIH Research Grants by Type, Fiscal Years 1967-1975

Fig. 11 NIH Competing Research Grant Applications Reviewed, Approved by Councils, and Awarded, Fiscal Years 1967-1975

Research project grants, once the life blood of biomedical research support and still the area from whence most innovative research arises fall into two categories:

1. Non-competing = those grants which have been approved for more than one year, with funds for future years committed and awarded annually contingent on availability of funds.

2. Competing applications for grant support which are subjected to peer review and are in direct competition for available funds for the current year and possibly for future commitments (as non-competing continuation grants above).

   a. New=applications for initial support of a research project.

   b. Supplemental=request for additional funding of an on-going project grant. May be for any number of reasons from administrative salary increases to change or increase in scope of the originally proposed parent project. If awarded, supplements usually run for the remainder (but cannot exceed) of the period committed for the parent grant.

   c. Renewal=programs which have reached the end of committed support but the applicant wishes to continue the same line of investigation (perhaps with minor to significant modifications) under the direction of the same principal investigator at the same grantee institution.

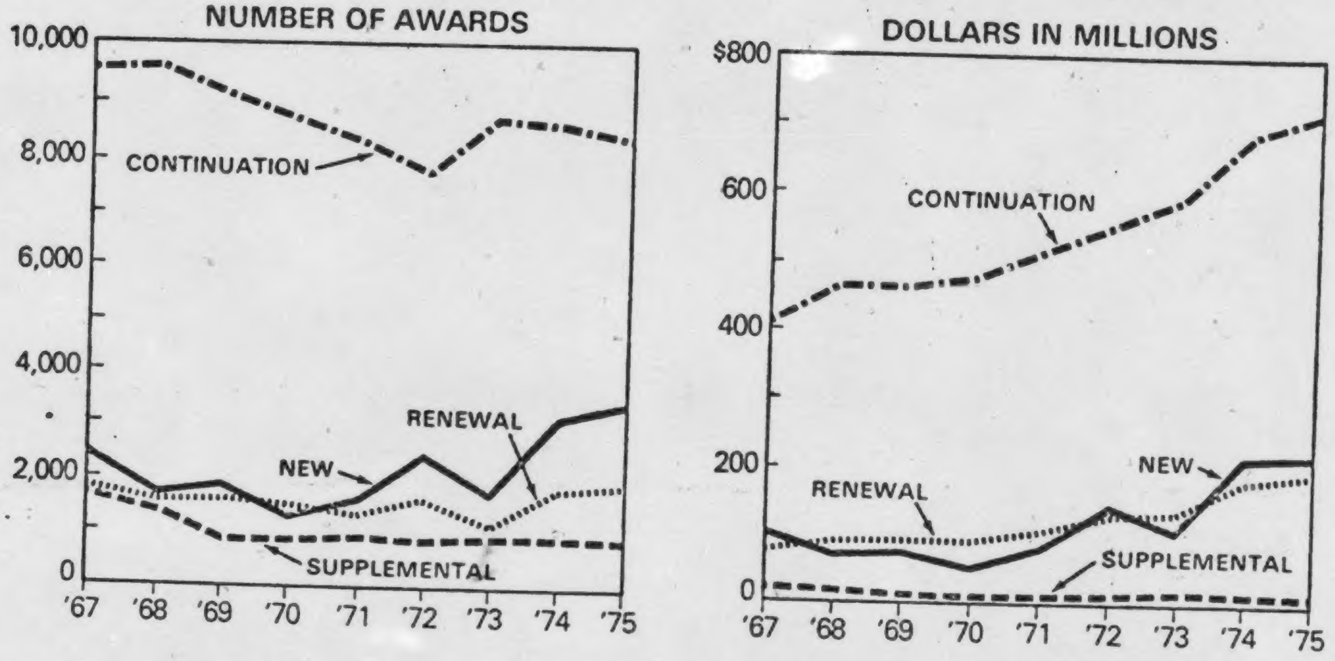
Unsurprisingly (in light of budgetary limitations and competitive pressures) requests for supplemental awards have not fared well in the recent past. Not only has the dollar amount of such grants remained stable (at a very low level) or perhaps even decreased, the number of supplemental awards has decreased significantly in the period 1967-1975.

The number of renewals has fluctuated from year to year within the same general range but there has been a significant increase in the level of funding for renewal grants from 1967-1975 because of the increased per grant costs, a direct reflection of inflationary influences more than increased scope of investigation, with perhaps some impact felt from the requirement for more sophisticated instrumentation, i.e., Newton's law of gravity required only an apple tree and a perceptive mind, whereas splitting the atom requires somewhat more sophisticated equipment and a small army of super-scientists.

Continuation of committed grant programs represents a significant portion of every institute's extramural budget. The striking impact of inflation can be seen in these programs because they carry within their budgets a significant component for personnel salaries (among the items most sensitive to inflation) as well as renewal of equipment which becomes ever more expensive. Thus, the dollar amount of a committed grant increases annually to support the same research effort. As the price per project goes up, there tends to be a concomitant decrease in the number of awards with future commitments and a decrease in the length of such commitments. In turn, shorter commitments require more frequent application as competing renewals and provide a mechanism for more frequent peer review of a wider representation of all the research proposed within chosen fields.

What might appear to the cynic as the step-child of the biomedical research "establishment" is, in fact its favored child. Recognizing the truism that initial research proposals are apt to be proposed by younger (perhaps more eager and creative) investigators, conscientious efforts have not only resulted in the increase of money poured into grants of this category, but the number of such awards has significantly increased (perhaps at the

Figure 10
NIH RESEARCH GRANTS BY TYPE, FISCAL YEARS 1967—1975*



*Excludes NLM. Includes research career program awards. All GRS programs (except Minority Biomedical Support Grants) are included under continuations.

expense of supplemental and continuation awards) from 1967 to 1975. The optimist might well regard this trend as recognition of the promise embodied in younger, perhaps better trained young minds and exemplifying perception and vision in creative administration of federal support of science portending yet undreamed of achievements and a better future for mankind. Contrary views are often as vehemently expressed that established scientists of recognized competence are being sold short by bureaucratic infatuation with neophyte "whizz kids" and their bright new "tinker toys."

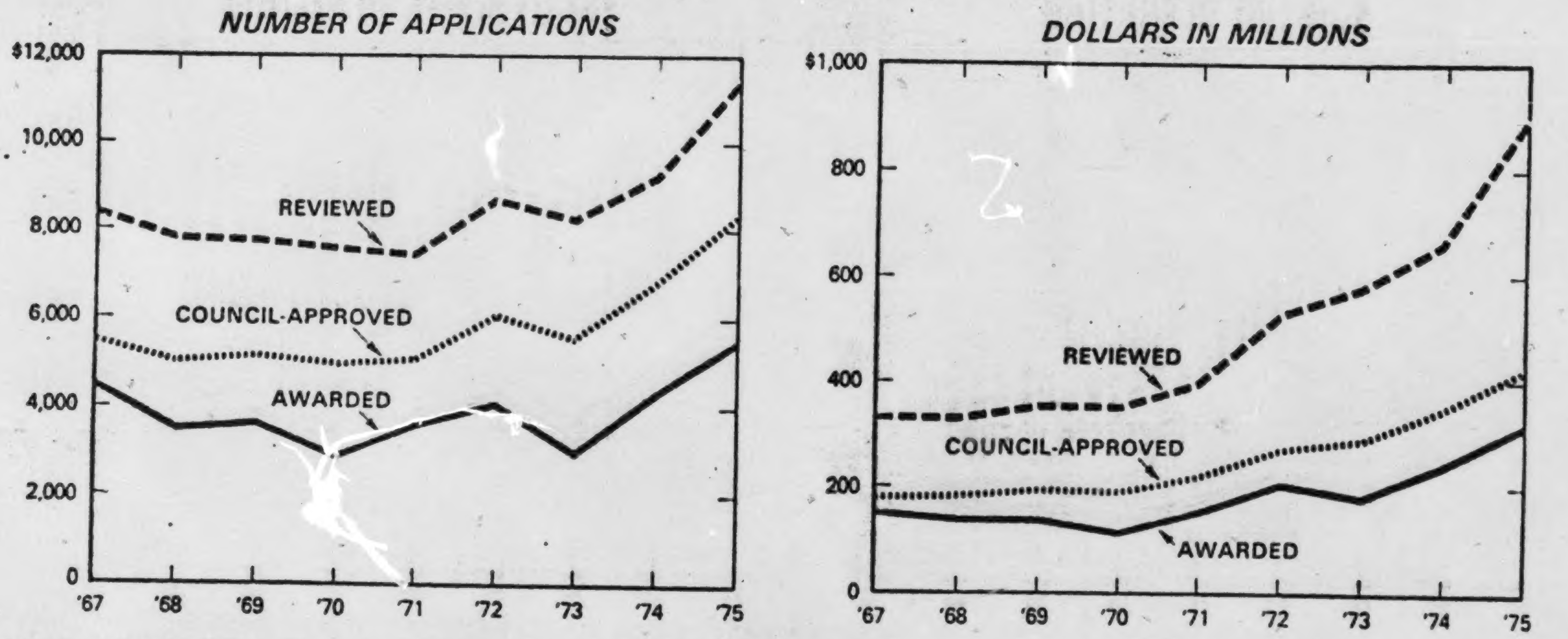
A discussion of Fig. 11 requires the clarification that of all the applications for grant support *some* are determined by administrative review not to fulfill the requirements of the type of program support requested, and are therefore returned to the applicant without being further processed through the system leading to "peer merit review." Those applications meeting published requirements for the program are processed and do undergo peer review which is discussed in greater detail in a later section of this treatise. After initial peer review, applications are reviewed by the appropriate Institute Advisory Council and judged on program relevance. No grant can be awarded *without* council approval. However, those approved by council are awarded in priority order only to the limit of available funds. Since the inception of the NIH grant program, there has each year been a significant backlog of approved, meritorious proposals which were not funded because of budgetary limitations.

In studying Fig. 11 one should keep in mind that the curve representing "reviewed" in essence means those applications accepted as complying with program requirements and subsequently reviewed by a peer initial review (IRG) group. The line labeled "council-approved" virtually represents those applications reviewed and approved by the peer review (IRG) group, for seldom does a council reverse the evaluation or recommendation of the initial review group. Thus, those indicated as awarded are those applications approved at two levels and enjoying a priority good enough to be reached by available funds. These are the blessed who have been subjected to "triple rigor." Often their less fortunate confreres succumb to "scientific rigor mortis."

Although the number of applications reviewed has significantly increased from 1967 to 1975 the percentage of approvals has remained fairly consistent at approximately 70% and the percentage of approvals subsequently funded has also been a fairly stable 70-71%. Therefore, of the applications accepted for review by NIH from 1967 to 1975 ap-

Figure 11

NIH COMPETING RESEARCH GRANT APPLICATIONS REVIEWED, APPROVED BY COUNCILS, AND AWARDED, FISCAL YEARS 1967—1975*



*All years include RCPAs, and exclude NLM, originals of amended applications, and applications awarded with budget periods of 24 months or more.

proximately 49-50% have been funded. This pattern would, therefore, account for increase in budget levels of comparable magnitude over this period if it were not for the ogre of inflation. Whereas the number of grants awarded in 1967 (4,200) increased to 5,800 in 1975 (38%), the money allocated to these grants rose from approximately $155 million in 1967 to some $300 million in 1975 (94% increase) so that the cost of the average research project grant in 1967 of $36,904 rose to $51,724 in 1975 reflecting a 40% increase in the cost per grant, probably more reflective of inflation than indicative of increased scope or excellence of research being performed.

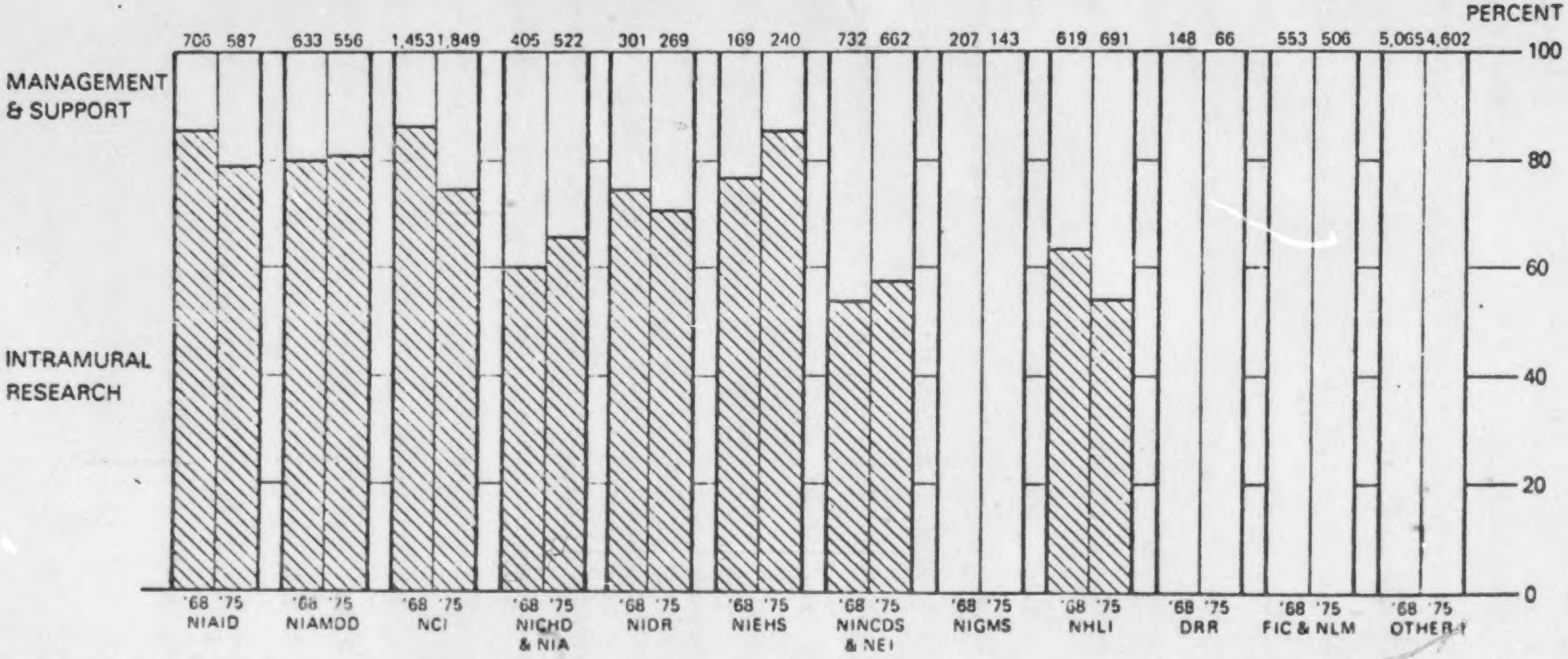
Fig. 12 NIH Permanent Full-Time Personnel by NIH Component and Function - June 30, 1968 and 1975

Whether employed in the intramural laboratories or as management and support staff, the vast majority of NIH personnel are highly professional, scientific careerists who enjoy the respect not only of their peers and confreres but also that of the biomedical scientific community with whom they intimately interact. One of the most striking observations to be made from this presentation is that, during a period when financial support of the many aspects of biomedical science increased many fold the full time personnel employed by NIH to administer the necessary programs actually decreased from 10,991 in 1968 to

Figure 12

NIH PERMANENT FULL-TIME PERSONNEL BY NIH COMPONENT AND FUNCTION

JUNE 30, 1968 AND 1975*



*Excludes consultants, members of councils, personnel exempt from ceilings, and those in non-pay status. †CC, DCRT, DRG, DRS, and OD.

10,106 in 1975, a loss of 885 positions, an 8% decline in staffing. When it is recognized that, except for those institutes or divisions with no intramural research which are clearly apparent on the graph, the remaining 10 Institutes have from 56% to 86% (average 71.5%) of their personnel in intramural laboratories and only 14% to 44% (average 28.5%) assigned to management, support and the administration of thousands of grant and contract supported programs comprising approximately 88% of total NIH expenditures for biomedical science research and development. By any measurement, this does not constitute bureaucratic hyperplasia nor diminution in the support of biomedical académe.

Use of Public Advisory Groups

There appears to be considerable validity to the opinion that "public advisory groups are directly influential in the administration of NIH programs for the benefit or convenience of the biomedical constituencies they represent." Unlike a college Board of Directors, none of these groups has policy making or enforcement authority. Although only advisory, the advice or recommendations of these bodies are seldom taken lightly and virtually never disregarded or countermanded. In the extremely rare incidence of a recommendation which is perceived to be adverse to programs or policy, diplomatic persuasion usually results in modification or withdrawal of such recommendations prior to formalization or documentation. Perhaps the finest achievement of an NIH administrator is the ability to interact (without appearing to control) with advisory groups representing divergent interest in such a manner as to accomplish program and organizational goals through the implementation of recommendations, enjoying support of advisory group members and the constituencies they represent. The fact that such support (usually in a spirit of warm fraternity) is routinely experienced attests to compatibility of professional orientation and scientific allegiancies of both the advisors and the program administrators.

To serve the diverse needs utilizing input from public advisors, three basic mechanisms or structures are employed. The first encompasses the so-called "standing committees or councils" which are authorized by specific legislation with specified structure, functions, membership numbers, and regularly scheduled meetings. These groups, once constituted, are virtually permanent with membership changing through the annual replacement of retiring members (usually no more than 1/3 the total membership). Membership on such groups may be for a period not to exceed four years and an individual cannot be re-appointed prior to one year after retirement from previous committee service. Nominations for membership on such groups originate from a multitude of sources including scientists in the subject fields, special interest groups, political partisans and even from program administrators. However, appointment to serve is made by the Secretary, DHEW.

Within the category described above reside all the Institute Advisory Councils, the formally constituted scientific peer review Study Sections, and a host of advisory committees at every level of administration from the Office of the Director, NIH through bureaus, institutes, divisions and in some cases even down to the branch level. The magnitude of intimacy of involvement in policy formulation and program implementation by NIH in its entirety can be appreciated when it is realized that more than 2,000 individual consultants serve on 161 such permanent committees and councils. Selection of memberships and committee functions are among the most conscientious concerns of NIH, never treated in a capricious or arbitrary manner. Membership includes scientists and physicians in the specialties subserved by the advisory groups as well as "interested lay" members drawn from business, finance and other sectors. Thus cardiologists, hematologists, pulmonary physiologists, epidemiologists and the like will be found on the National Heart and Lung Advisory Council, whereas oncologists, physiologists, toxicologists, pharmaceutical chemists and radiologists and "lay" leaders like Mrs. Mary Lasker serve on the National Cancer Advisory Board. The scientific peer review Study Sections are established to evaluate applications within clearly defined scientific or specialty disciplines and are populated by scientists or specialists recognized as leaders or acknowledged authorities in the subject disciplines. Because of the rigorous scientific evaluation required of these groups, there is seldom "lay" representation on them. Perhaps indicative of the true relationships within all the above assemblages is the statement made in the official NIH publication listing these groups which states "a government official is present at all meetings," or the stronger indication that "the agenda shall have the advance approval of a government official."

The second category of advisory groups are the many "ad hoc" committees which serve a number of functions not realistically assignable to the "standing" groups. Special evaluations or program interests can often be most effectively handled by ad hoc groups. Membership of such groups is usually chosen by the executive secretary or program officer with attention paid to specialty or disciplinary competence required to perform the appointed task, be it application review or program evaluation. Ad hoc groups are not chartered, are temporary and constituted to perform clearly specified tasks. Additional discussion of such functions will be made later in this section and in the section on peer review.

"Working groups" or individual consultants are utilized to assist in the performances of a wide range of evaluative, "trouble shooting" or technical assistance tasks. They, too, are ad hoc and selected on the basis of their expertise to satisfy the requirements for accomplishing the task at hand.

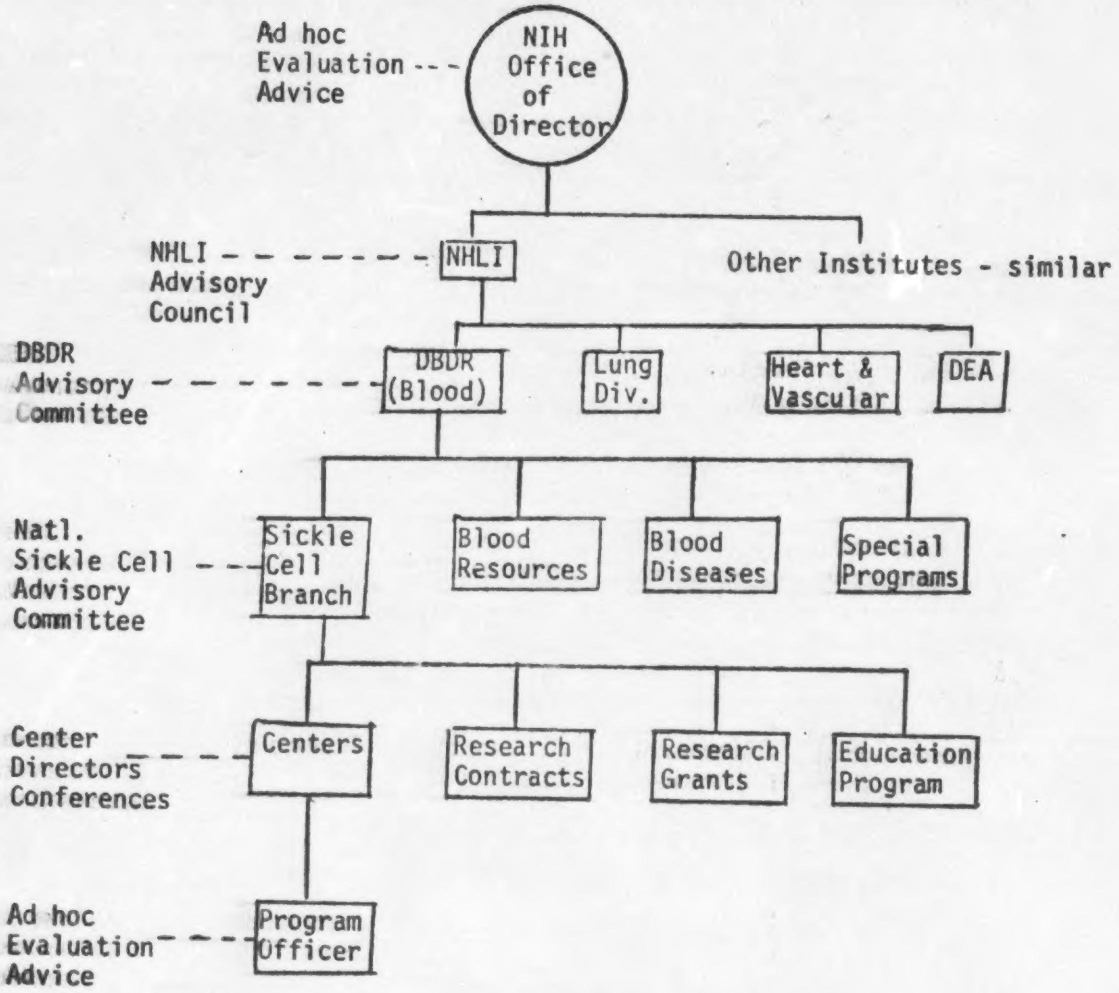
An example of the many levels of input by public advisors is shown diagramatically on page 41 following. In summary, it should be clearly recognized that advisors serve an essential purpose at all levels and in virtually every function of NIH, often at real personal sacrifice (honoraria usually are only a fraction of their normal income rate) motivated by genuine dedication to biomedical science, a desire to remain on the frontier of the administration of their specialty and perhaps a smattering of altruism. Extensive utilization is made of advisory groups for the following functions:

1. Program concept or policy formulation.
2. Peer review of application~~s~~ including site visits.
3. Program approval required for awards.
4. Program implementation assistance.
5. Program evaluation and guidance.
6. "Trouble shooting," special problems, technical assistance.

Thus, these groups afford NIH access to a reservoir of competence in every facet of biomedical science which would be impossible to duplicate by any other known mechanism and without which NIH programs could not be competently conducted by its currently limited staff.

A graphic example indicating different levels of utilization of public advisory groups is shown in the following diagram:

NIH - USE OF PUBLIC ADVISORY GROUPS
(an example)


Ad hoc Evaluation Advice
NIH Office of Director
NHLI Advisory Council
NHLI
Other Institutes - similar
DBDR Advisory Committee
DBDR (Blood)
Lung Div.
Heart & Vascular
DEA
Natl. Sickle Cell Advisory Committee
Sickle Cell Branch
Blood Resources
Blood Diseases
Special Programs
Center Directors Conferences
Centers
Research Contracts
Research Grants
Education Program
Ad hoc Evaluation Advice
Program Officer

NIH Intramural Research

Whereas its original mandate was for the care of sick and disabled seamen, findings in microbiology, bacteriology, epidemiology, etc., soon stimulated the pursuit of investigation into the causes of epidemic and contagious diseases. The earliest of these efforts were directed toward yellow fever, cholera, leprosy, tuberculosis, tuloremia, typhus, typhoid and malaria. Such research was conducted primarily within agency laboratories or in field investigations conducted by agency staff. Funding levels were modest and research closely identified with and circumscribed by the discipline and interests of the agency director. The modesty of the Federal Budget for non-military expenditures was dramatically reflected over the years prior to World War II. Even though employed by the bureaucracy, intramural scientists at NIH and its predecessor agencies clearly identified most strongly with their scientific peers. They were scientists (of whatever discipline) first and government employees secondly, with their allegiances predominantly to their scientific discipline with concessions made to the bureaucracy grudgingly and only as dictated by the expediencies for economic survival.

Enactment of the Public Health Service Act, establishing NIH as a separate agency, enlarging its laboratory facilities and moving it *in toto* to Bethesda, Maryland, in 1944 marked the recognition and reward for research efforts past but served as the cornerstone for building a biomedical research establishment of unprecedented magnitude, scope, and achievement. From its meager beginnings the intramural research program rose to approximately

$15 million in 1955 and reached $225 million in 1975, the scope of investigations almost infinite. Euphemisms employed by staff referring to "the main campus of NIH in Bethesda," "scientific peer discussions," "value of publication," etc., clearly reveal the psychology of this "Prima Donna" scientific-profession oriented agency in which half or more of the staff hold graduate degrees and are strongly identified with academia. After self appraisal, the NIH intramural research staff unabashedly states that "by size or influence, or any combination of the two, NIH appears to be the single most productive biomedical research institution in the United States by far."

Although the above statement might appear to be egocentric braggadocio, it is more accurately reflective of the self-imposed scientific elitism so fervently expoused by the members of this prestigious group. Most of the Institutes of NIH conduct intramural research within their own laboratories but the inhabitants of these laboratories actively engage in scientific discussion with their confreres regardless of employing agencies, clearly reflecting the fraternalism of scientific professionalism superimposed on organizational structure. This aura of esoteric academe is further reinforced by employment and staffing practices as well as the method for review of research program evaluation and approval.

Program review, evaluation and innovation. The various laboratories at NIH, almost regardless of the Institute supporting them, tend to be the inviolate fiefdom of the senior scientist or scientific director of the particular laboratory, and activities therein pursue research virtually restricted to his or her special interests. Nevertheless, there is a formal review of every separate scientific project in the intramural program each year. Individual scientists present summaries describing what has been done and what is planned for the immediate future. The critical review of these summary reports by the section and laboratory chiefs, by the Scientific Directors of the several institutes, and, in some degree by the Office of the Deputy Director for Science, NIH, provides the first and most regular of the steps in the review process. This vertical review heirarchy provides ample opportunity for each supervisory layer to render judgment and influence program conduct and/or modification. Although investigational plans may be modified in this review process, the investigator is assured of financial support for his research, whatever its final form may be. Because of the practices employed in selection and promotion (as discussed below under an appropriate section) it is inconsistent, and indeed directly conflictory with NIH intramural philosophy for a staff scientist to be denied funds for his research pursuits.

Perhaps the most important review of the quality of science and innovation produced by intramural NIH is that exercised by the editorial boards of prestigious scientific journals. The population from which such boards of editors come is the same as that from which members of Initial Review Groups (in the extramural program peer review) are chosen. Therefore, much the same reviewers of grant applications are also involved in reviewing the products of research generated by intramural scientists. Intramural scientists constitute 3.22% of the total membership of the Federation of American Societies for Experimental Biology (consisting of six prestigious societies representing the majority of biomedical science). Intramural NIH research has, according to a recent study, produced 7.49% of all review articles appearing in 12 major biomedical review journals, and 5.12% of all articles appearing in a list of 20 biomedical journals which have the highest influence/publication. The intramural research fraternity at NIH is justifiably proud of the fact that three of its members have received Nobel prizes for research findings made in NIH laboratories and the fact that many other laureates have collaborated with and/or been influenced by the intramural research programs of this agency.

> 1968 - Marshall W. Nirenberg - Physiology or Medicine - Translation of the genetic code and its function in protein synthesis.
>
> 1970 - Julius Axelrod - Physiology or Medicine - Discoveries concerning transmitter substances in nerve terminals and mechanisms for their storage, release and deactivation.
>
> 1972 - Christian B. Anfinsen - Chemistry - Studies of ribonuclease, particularly the relationship between amino acid sequences and the biologically active conformation (of the enzyme molecules).

Staffing and manpower management. Perhaps the discussion of personnel and manpower management within the intramural program of NIH would form a logical portion of a discussion of the overall or totality of manpower management throughout the agency but is included in this treatise to aid in the more thorough portrayal of the philosophies and personality of the intramural establishment and the ramifications of this unique psychological milieu. Within this realm dwell "people" and "scientists" who not only perform different functions but are, by definition, distinct in their attributes, utility and status within the system. "People" are those individuals performing "support" functions such as typing, laboratory technician, diener, equipment repair and such like. They are governed by the standard Civil Service Commission system and its regulations with each set of functions falling into an appropriate, clearly defined series and individuals within that series progressing within the grade limitations of the series through rather standardized or routine work performance evaluation and competitive application for openings at least in theory consistent with the CSC merit promotion system. Because of the close relation to laboratory duties of most of these series, few except those in clerical categories leave this sanctum for assignments in the extramural programs.

Those annointed, classified as "scientists," though frequenting the same space, live in a different world, governed by different rules and subject to different evaluative criteria. Hierarchy and management in this group provide the anomaly of a formalized, standard bureaucratic staffing system (these are Civil Service employees) administered by academic standards of professorial rank, tenure and perquisites. Membership in this select fraternity may be achieved through two routes. The less arduous but more restrictive may be referred to as "direct hire" and is reserved for those recognized as accomplished, established scientist who are worthy of near-full professorial rank or are indeed leaders in their respective fields. Such personages are recruited for higher level positions as laboratory, section or division chiefs, coming fully endowed with prestige and accorded appropriate deferences by all.

A most interesting assemblage more demonstrative of the system as conducted, are those "who have come up through the ranks." If religion can be defined as: "any specific system of belief, worship, conduct, etc., often involving a code of ethics and a philosophy," then science as practiced in the intramural laboratories of NIH is a religion replete with gurus and disciples in which "many are culled and few are chosen." The prestige enjoyed by identification with this prestigious host attracts an extraordinarily large number of applications from pre-Ph.D. and new-Ph.D. candidates for positions as research associates who enjoy the privilege of working with and under the often rigid surveillance of an established scientist. Usually hired at GS-11 or lower grade these persons are clearly in a non-tenured status comparable to instructors in universities. After an appropriate period of servitude (usually at the discretion of the supervisor) a day of reckoning is reached upon which the candidate is either advanced to junior research scientist or is advised that his period of training is complete and offers for employment in académe may be seriously considered. Though at times traumatic to the candidate, this exclusion from the hallowed halls is viewed by his seniors as an effective means of enriching the pool of research personnel available to "the better" universities and, indeed, the prestige of having matriculated at NIH is a decided status increment, and such alumni seldom have difficulty in placement in institutions of their choosing.

Once initiated into the order, progression up the promotional ladder follows much the same pattern as professorial promotion in the academic world. Every scientific promotion above the level of GS-11 and every initial action providing prolonged variable incentive pay (above normal GS rates) to commissioned medical officers is reviewed by the Scientific Directors' group. Review is invariably chiefly related to the science which the candidate has accomplished (with appropriate publication) and is conducting. The bibliography of the candidate is critically analyzed, not merely with respect to numbers of publications but with respect to the quality of the journals in which these have appeared and, in many instances, to the content of the individual papers. The depth, frequency, and severity of such evaluative practices on which promotions depend may both stimulate the young investigator to strive for maximum scientific (and literary) productivity and tend to retard the rate of promotion. Despite the freedom with which NIH alumni may move to academic laboratories and, indeed the constant recruitment pressure applied to them by universities, there appears to be strong loyalty and permanence of the elite group. Stability of personnel and progressional system tends to insure productivity of younger researchers but also contributes to rigidity and ossification of the most senior chiefs who might make a greater contribution by abdicating the role of scientific "Herr geheimrat" and entering the broader arena of administration of scientific programs. These "senior scientific citizens" could be invaluable in advisory capacities even though they may have exhausted their "bench sciences" productivity and become programmatic "dead wood."

Extramural Support Programs

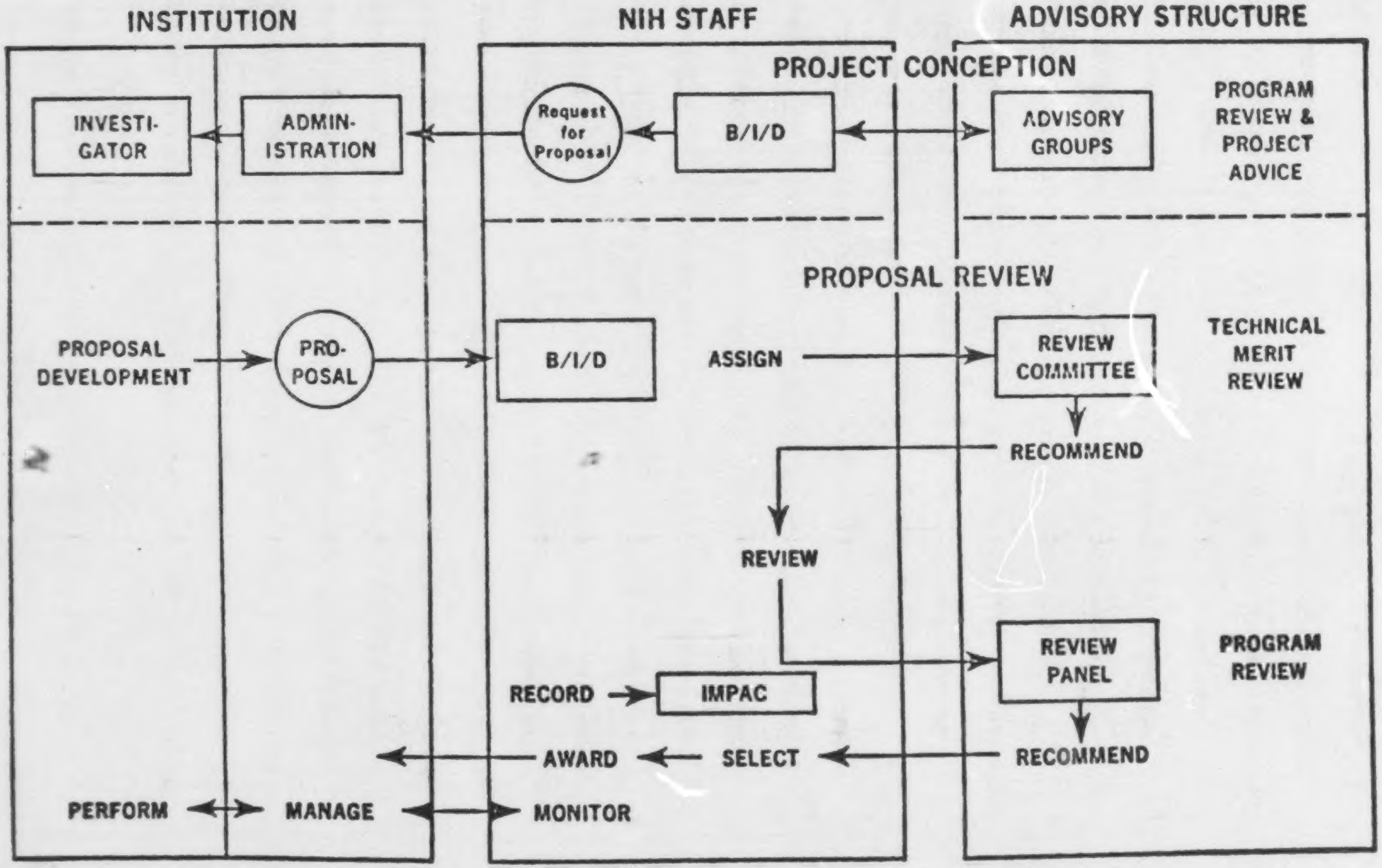
The support of biomedical research by the National Institutes of Health through a plethora of program types utilizing both contract and granting mechanisms is, like a peacock, a many splendored thing, beauteous to behold, replete with all the hues of the scientific rainbow, and whose cries of anguish have been heeded throughout the legislative chambers and whose nurture has been unstintingly ministered to by potentates. A comprehensive treatment of the variety of programs supported is beyond the scope of this presentation but can be appreciated partially by the recognition that there are 17 types of research project grant programs alone. In addition there are fellowships and training programs, resource and center programs, general research support, construction and career development programs (presented in Appendix C) which cover every perceived need for the support of biomedical science development and productivity of significant achievement.

Grant vs. Contract

As alluded to earlier the grant mechanism is most compatible with the accepted philosophy at NIH that "only worthy proposals and competent applicants can survive the rigorous dual, peer review evaluation as conducted at NIH and the innovative creativity of such individuals and programs is best fostered by freedom for intellectual pursuit with a minimum of administrative stricture and interference." However there arise problems demanding investigation which are perhaps outside the interest of investigator initiated programs or are inadequately covered by such efforts. The contract mechanism has been utilized to "purchase" research in certain areas since the inception of the early Cancer contracts and the first legislation authorizing NIH to support research outside its own laboratories. However, to date contracts have been utilized only "to develop and/or apply new knowledge or to test, screen or evaluate a product, material, device, or component for use by the scientific community." This concept has been broadened slightly to include "targeted" research such as development of improved diagnostic methodology or to determine the efficacy of a therapeutic regimen.

The development, initiation, evaluation and conduct of contract programs may be visualized in the flow chart following this page and herein described. Review of the total program goals of an Institute by staff and/or special advisory groups reveals areas requiring additional emphasis or research initiation. These needs initiate the formulation by staff of a Request for

REVIEW PROCESS FOR NIH EXTRAMURAL AWARDS - CONTRACTS


INSTITUTION
NIH STAFF
ADVISORY STRUCTURE
PROJECT CONCEPTION
INVESTI-GATOR
ADMIN-ISTRATION
Request for Proposal
B/I/D
ADVISORY GROUPS
PROGRAM REVIEW & PROJECT ADVICE
PROPOSAL REVIEW
PROPOSAL DEVELOPMENT
PRO-POSAL
B/I/D
ASSIGN
REVIEW COMMITTEE
TECHNICAL MERIT REVIEW
RECOMMEND
REVIEW
REVIEW PANEL
PROGRAM REVIEW
RECORD
IMPAC
AWARD
SELECT
RECOMMEND
PERFORM
MANAGE
MONITOR

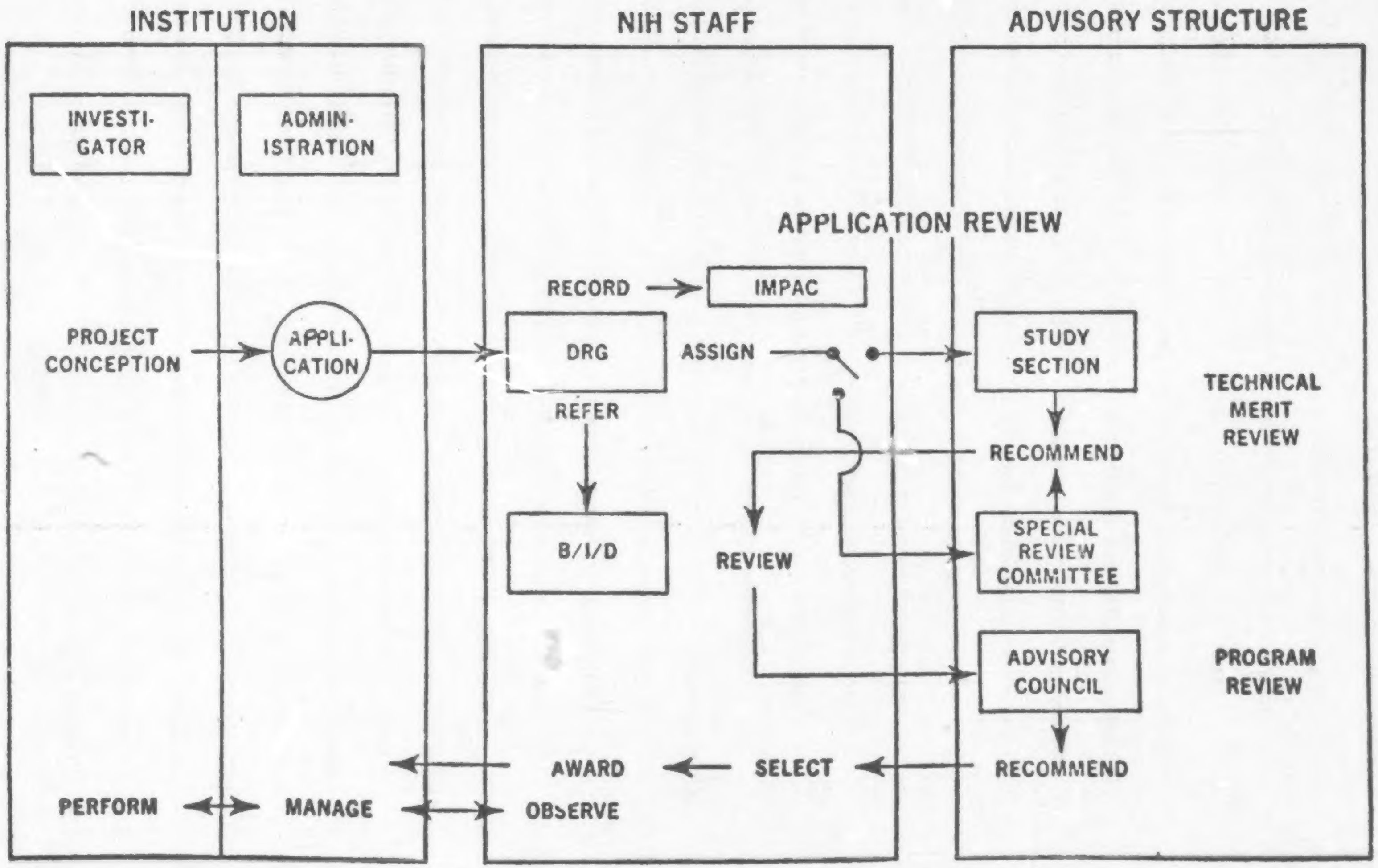
Proposal clearly enunciating program needs, conditions to be fulfilled and, in many cases, every protocol to be followed, which are published in the Commerce Business Daily and widely distributed to appropriate institutions, administrators, and investigators. Proposals developed by investigators in accordance with these guidelines are then submitted to the appropriate component (B/I/D) and assigned to a review committee composed of specialists in the specific area of investigation under consideration who perform a technical merit review to determine scientific adequacy of the proposal and likelihood of goal achievement. This is followed by staff review to determine compliance with guidelines and a second panel review to determine appropriateness to achievement of program goals. Recommendations resulting from these reviews result in the selection of awardees and staff negotiations establish the funding level and conditions of the contract. Upon award, pertinent information is incoded into the NIH information retrieval system (IMPAC) and conduct of the program begun with frequent reporting from the contractor and monitoring by NIH staff. Although contract programs may extend for more than one year, each is re-evaluated and re-negotiated annually and may be funded only one year at a time. Besides the reduction in investigator freedom and initiative and the increased staff surveillance and direction, the most significant distinction between grants and contracts lies in the fact that contracts are not reviewed by Institute Advisory Councils whereas grants can not be awarded without approval of the appropriate (B/I/D) Advisory Council.

Applications for grant support (regardless of program type, i.e., research project, center, training program, etc.) are originated by the investigator or proposed program director according to program guidelines issued by NIH. After approval by the administration (see also regulatory process section) of the originating institution the application is sent to the Division of Research Grants, NIH, whose staff record pertinent data in the computer (IMPAC) system and assign the application simultaneously to an initial review group and the appropriate component (B/I/D) according to discipline and program as reflected in Appendix B. In those instances where an application proposes activities within the purview of more than one institute, a dual assignment is made with the primary assignment to the institute with predominant programmatic relevance and the secondary assignee being the institute of lesser apparent involvement. Utilization of this stratagem is an important factor in fostering the free flow of applications through the system with maximum opportunity for benefit to the applicant and availability of good projects to the institutes. In the event of approval by the initial review group, a dually assigned application may be funded by the primary institute or relinquished to the secondary assignee who may choose to process it through to funding without the necessity of repeating the technical merit review.

As shown on the flow chart, the initial review group assignment may be made to one of the established study sections or to a special review committee (a more detailed treatment of these groups is presented under Peer Review-How Now) whose body of specialists consultants in the subject discipline evaluate the application in terms of its technical scientific merit. This review results either in disapproval or approval with a priority assigned indicative of the relative excellence of the proposal. Simultaneously the application and IRG recommendation are evaluated for program relevance by institute staff and subsequently both technical merit and program recommendations are transmitted to the Advisory Council for review and recommendation. Seldom does a Council reverse an IRG recommendation but an application may be deferred for additional information, site visit evaluation or reassignment and re-review. Upon recommendation by Council and additional staff input in compliance with Council recommendation, grants are awarded to the grantee institution on behalf of the investigator (in priority order within the limitations of available funds) for conduct of the project according to the investigator-originated protocol. Staff of the awarding institute continually observe program activities and attend to required management needs but assume a more supportive supervision than exercised in contract programs.

In conclusion, distinctions between the criteria determining whether the grant or contract mechanism is to be used for project support and significant differences in the character-

REVIEW PROCESS FOR NIH EXTRAMURAL AWARDS - GRANTS


INSTITUTION
NIH STAFF
ADVISORY STRUCTURE
INVESTIGATOR
ADMINISTRATION
APPLICATION REVIEW
RECORD
IMPAC
PROJECT CONCEPTION
APPLICATION
DRG
ASSIGN
STUDY SECTION
TECHNICAL MERIT REVIEW
REFER
RECOMMEND
B/I/D
REVIEW
SPECIAL REVIEW COMMITTEE
ADVISORY COUNCIL
PROGRAM REVIEW
AWARD
SELECT
RECOMMEND
PERFORM
MANAGE
OBSERVE

istics of such programs are presented in tabular form below:

GRANT OR CONTRACT?

Criteria for Determining Instrument of Choice

Grant	Contract
Project conceived by investigator	Project conceived by NIH
NIH supports or assists	NIH procures service or product
Performer defines details and retains scientific freedom	NIH exercises direction or control
NIH maintains cognizance	NIH closely monitors

Some Contrasting Project Characteristics

Grant	Contract
Diversified program	Targeted program
Exploratory project	Developmental project
Outcome defined but unpredictable	Outcome predictable
Extends knowledge base	Applies existing knowledge
Flexible approach	Structured approach
Simple NIH management	Intensive management
Difficult evaluation	Easy evaluation
Single institution	Multiple performers
Few people involved	Many people involved

Peer Review-How Now?

The Public Health Service Act of 1944 authorized the expenditure of funds for grants to support biomedical research but set forth no guidelines for the selection of recipients of such awards. Thus, the staff of NIH were (forced or at liberty) to design and implement such a selection process. Their strong professional ties with scientific predilection dictated "scientific peer review" as superior to and separable from other evaluative considerations. Initial review groups constituted of scientists in a specific field or discipline were made responsible for the scientific merit evaluation of applications in their representative areas of expertise. National Advisory Councils (for each of the awarding Institutes) with memberships of scientists and distinguished leaders from the "lay-public" sector were charged with policy recommendations leading to programmatic emphasis and final approval for funding of applications. These two reviewing bodies constitute the "dual peer review" system for the evaluation of the many types of applications for grant support. Although a partial reiteration of the preceding section, discussion of a special problem follows. Further discussion in this paper will be restricted to applications for research project grants (R-01) as the prototype and exemplar of the system described simplistically below:

1. Applications received by the Division of Research Grants are assigned to an Initial Review Group (based

on scientific discipline) and to the appropriate Bureau, Institute or Division (dependent on program content).

2. Each application is simultaneously evaluated for technical merit by the Initial Review Group and reviewed by B/I/D staff for program relevance.

3. Summary statement containing IRG recommendation evaluation and priority accompanied by B/I/D staff recommendation transmitted to appropriate Advisory Council.

4. Advisory Council recommendation sent to B/I/D staff.

5. B/I/D staff make final programmatic review and implement appropriate action.

6. Award made to successful applicant institution which has fiscal responsibility for conduct of proposed program under direct supervision of (scientific) Principal Investigator.

The magnitude and scope of this effort can be appreciated in light of these data:

1. An average of 10,000 applications for research project grants are reviewed annually by:

2. 54 scientific discipline study sections plus special review groups involving:

3. More than 2,000 consultants in review group and advisory councils in addition to:

4. Staff of all the awarding units.

Application assignments for March '74 Council follows:

NIAID	Council	received	reviews	from	22	study	sections.
NIAMDD	"	"	"	"	32	"	"
NCI	"	"	"	"	32	"	"
NIDR	"	"	"	"	12	"	"
NICHD	"	"	"	"	32	"	"
NEI	"	"	"	"	14	"	"
NIEHS	"	"	"	"	13	"	"
NHLI	"	"	"	"	29	"	"
NINDS	"	"	"	"	30	"	"
NIGMS	"	"	"	"	23	"	"

The data excludes summary statements from SSS and NIMH study sections.

Characteristics of Review Methods: (note--each category represents a generalized situation; ad hoc and special review groups permit DRG and/or B/I/D's to satisfactorily do any or all activities)

Centralized - Division of Research Grants

1. Serves all B/I/D's*
2. Usually discipline oriented
3. Technical merit review based on standards of given scientific discipline
4. Easily monitored by NIH (for procedures, quality of review)
5. Committee removed from program planning and evaluation
6. Predominately oriented toward individual project

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* B/I/D --- Bureau, Institute or Division

grants

7. Little program or B/I/D staff advice

8. Usually single mechanism

Centralized - Bureau/Institute/Division

1. Serves on B/I/D

2. Usually multidisciplinary

3. Technical merit review considers program objectives and criteria

4. Easily monitored by B/I/D

5. Committee available for program planning and evaluation

6. Oriented toward special program grants

7. Program staff advice

Decentralized - B/I/D Programs

1. Serves one program within B/I/D

2. Usually multidisciplinary

3. Technical merit review includes program objectives and criteria

4. Easily monitored by Program Chiefs

5. Committee frequently participates in program planning and evaluation

6. Oriented toward special program goals

7. Program staff involvement

8. Facilitates coordination of program mechanisms

Review Procedures of Other Federal Agencies - A Comparison

Other Federal agencies in addition to the National Institute of Health have extramural programs for research and development in the life sciences or health fields supported by grants, contracts, or agreements. The following summaries are based upon informal conversations with agency staff; they are not official statements of the procedures of the agencies contacted.

Officer of Naval Research: ONR Divisions support both mission-oriented basic research and applied R & D. One Division allocating about $3 million per year relied on technical staff review. The Biological and Medical Sciences Division with a very small technical staff contracts with the American Institute for Biological Sciences (AIBS) for peer review on an *ad hoc* basis. The AIBS convenes committees of qualified specialists as required by the Division to screen proposals for contracts and cooperative agreements, totaling about $14 to $15 million per year. On a case by case basis, staff review only may be used.

U.S. Department of Agriculture: The Department of Agriculture when surveyed, funded only $2 to $5 million in extramural projects using grants, contracts, or cooperative agreements. Outside opinions were obtained at the option of staff but staff review was the usual mode. (A study of the USDA intramural and extramural research activities Report of the Committee on Research Advisory to the U.S. Department of Agriculture, 1972) recommended that "... this program be administered in such a way that research proposals are subjected to evaluation by peer panels of selected scientists drawn from those eligible for support..." This and other recommendations were under review of USDA.)

NASA--Office of Life Sciences: This Office reviews in the range of 100 to 500 R & D and engineering proposals each year and funds such projects at the level of about $40 to $50 million per year using both grants and contracts for non-profit institutions. The Office contracts with the AIBS for peer review. The AIBS selects members and conducts panel reviews on a scheduled basis and forwards summary reports of these evaluations to NASA with approved applications ranked in recommended order for funding, from 1-4.

Atomic Energy Commission, Division of Biomedical and Environmental Research: This Division funds about $17 to $20 million each year in extramural programs supported under contracts or "special research agreements." The Division uses a highly-structured reader system. Staff committees rank proposals based upon staff reports prepared from readers' opinions.

Food and Drug Administration: The FDA follows the NIH peer review procedure to allocate about $3 million per year for 50 to 60 projects. There is a dual review provision, with program committees providing a second level of review following technical review, either by NIH study sections or by FDA study sections. (The Bureau of Radiological Health uses technical panels only with the secondary review carried out only by staff.)

National Science Foundation: The various Divisions of NSF use different review procedures. The Division of Biological and Medical Sciences, with an annual budget of about $60 million, reviewing up to about 3000 proposals per year, utilizes committees or panels. Other NSF programs, such as those in physics and chemistry, rely upon readers but have established technical program advisory committees which are responsible for program overview. The individual members of these committees also serve as readers for the review of proposals.

A Task Group established by NSF to evaluate the peer review system of NSF, which reported October 1, 1973, concluded that the present peer review systems, regardless of type employed, seemed generally satisfactory as they are applied to individual research proposals.

An evaluative study was suggested by some members of the study group. Such a study would be most useful if it were to consider questions such as:

1. Whether the scientific community is adequately informed about NSF and participates effectively in the grant-making process;
2. Whether the grant-making process may discriminate against the new and imaginative, especially those projects which fall between traditional disciplines;
3. Whether there may be bias toward or against certain forms of academic or non-academic science; or
4. What effect the recent shift from affluence to scarcity may be having on the decision-making processes.

Events Prior to OMB Criticism: Under the imaginative administration of Dr. James Shannon with special interest group support led by Mary Lasker, all programs of NIH burgeoned through the benevolent support of Senator Lister Hill and Representative John Fogarty, chairmen of the Senate and House of Representatives Appropriations Committees respectively. A respectable series of Congressional investigations were initiated and reports rendered to appropriate legislative and executive authorities through the years 1960-67. However, these were more supportive than critical of NIH and its conduct of affairs for the benefit of the nation's health. Some adjustments were made in administrative and technical procedures but the NIH "Peer Review System" remained unscathed and virtually unchanged. With few exceptions, each year's appropriation was greater than the preceeding, most meritorious projects were funded, and there was little complaint.

With the death of Fogarty and the retirement of Hill and Shannon in 1967-68 coupled with inflation, recession and escalation of defense expenditures, the biomedical research community fell upon hard times. Many had escalated salaries and other costs to the point of pricing themselves out of the market. Many applicants, though approved on technical merit, were not funded because of budget limitations. Finding their pet projects without support was exceedingly traumatic to many in biomedical research,and they seized whatever avenue available to air their dissatisfaction with the system that left them thus destitute.

OMB Issue and Transmittal Memorandum - 1973: Perhaps in response to the several complaints, but more likely in an attempt to discharge its perceived duty as the regulatory or supervisory arm of the Executive Branch, the Office of Management and Budget conducted its own investigation into the management of NIH, and on April 3, 1973, issued a memorandum with specific criticisms of the NIH peer review system:

1. The system does not assure administrative responsibility for the allocation of Federal research funds by relying on the "collective judgment" of consultants -- the advisory committees -- who are convened only three times a year.
2. The process is largely reactive to the initiative, interests or whims of individual researchers and therefore is not readily compatible with targeted or directed research to achieve specific national objectives.
3. The participatory process produces an unavoidable conflict of interest situation for the individual scientists who serve as consultants because they determine the allocation of research funds that they also receive.
4. The participatory process produces a large clientele group that has a personal interest in the continuation of the process and the increase of appropriations at its disposal.
5. Over the years the process has tended to concentrate research and scientific advisers in a few select institutions. Of total NIH research award funds in 1971, 46% went to the top 25 grantee in-

stitutions, while over 300 institutions received such funds.

6. The system currently operates largely independently of administrative direction for the allocation of research funds.

7. Because it uses subjective measures of judgment, and thereby defines "scientific merit or quality" for itself, the system is not subject to objective measures of assessment.

8. The approval and rating system used by the IRG's produces a large number of "approved but unfunded" applications that are often used to support the need for more research funds. In FY 1972, for instance, 2,480 research grant applications were reviewed, 2,053 were approved, and 1,582 were funded, leaving 471 "approved but unfunded" applications. In addition, the approval is taken to be a standard of measurement for scientific quality for other purposes throughout the country.

Recommendations were made in which it was stated that "any such alternatives -- including abolition of the peer review system -- would have the effect of lessening the control of the peer review process or of placing controls and safeguards on its operation." The possibilities offered were:

1. Abolish the Peer Review Process, Relying Completely on Administrative Review. This would be the ultimate in return to administrative control. Legislation would

be necessary to remove the requirement for advisory council approval of research grants from the PHS Act. Alternatively, a dual review system could be maintained using NIH staff instead of outside consultants, but perhaps with less aggregate scientific competence involved.

2. Prohibit Consultants from Receiving Research Funds while Serving or for a Period of Time after Serving on Advisory Committees. This would probably be a less direct way of achieving the first alternative. There would be little ultimate gain in administrative control under this alternative. Participation on advisory committees would probably become less desirable if research support for members is circumscribed.

3. Seek Legislation to Exempt Grants from Advisory Council Approval. Such legislative provisions are now in effect with respect to grants of less than $35,000 in the Heart and Cancer institutes. If such provisions were extended to all research institutes, 51% of grants and 18% of dollars would be partially removed from peer review. Such action would, however, increase administrative responsibilities for a portion of the research funds. As long as peer review is the predominate method of review, however, an exemption may have little effect on the overall results of the process.

4. Use NIH/NIMH Staff for Initial Review with con-

sultants used only on an ad hoc basis. As in the first alternative, less aggregate scientific knowledge may go into the review process, but administrative control and responsibility would increase, and costs and potential conflicts of interests would decrease.

5. Use only numerical ratings by IRG's without "approval" or disapproval. If the numerical rating of scientific merit were made public rather than the "approval" or "disapproval" designation, the problems associated with the "approved but unfunded dilemma" could be eliminated and the "opprobrium" attached to disapproval would be eliminated as well.

6. Change membership of initial review groups after every two or four sessions. This would broaden involvement from the scientific community and lessen or tend to equalize the bias of these groups. It might increase the staff administrative burden for grant review.

7. Use a random anonymous review system. Instead of convening standing IRG's, reviews could be conducted by mail by randomly selected anonymous reviewers. This would maintain the involvement of an even larger portion of the scientific community.

8. Strengthen administrative accountability. HEW could establish an open planning and review process by which research directors set research objectives or goals and then review progress against these objectives semi-annually. This would assure a more active role by the directors of

the research programs in exercising administrative discretion to direct the allocation of research funds.

NIH Reaction to OMB Charges: The above criticisms reached NIH at what would appear a most inopportune time: between the resignation January 21, 1973, of Dr. Marston as Director of NIH and the assumption of this position by Dr. Robert Stone May 29, 1973. However, NIH was anything but leaderless, the senior staff positions being filled by a cadre of highly capable career professionals thoroughly familiar with the entire review process. Careful analysis was made of each item in the OMB criticisms and recommendations and on April 11, 1973, official response from the Office of the Director was issued. In this response meticulous attention was given to each detail and the OMB comments discounted individually. With ample supportive data, each OMB criticism was shown to be patently false, the result of inadequate information, misinterpretation of facts or based on erroneous or invalid data. Recommendations were similarly treated and shown to be conducive to no improvement or to actual detriment to the fair review and administration of programs.

Even though (at least theoretically) the issue was thus disposed of, sensitivities and awareness had been aroused. Having developed under the ministrations and surveillance of 12 legislative committees (32 subcommittees) and powerful interest groups in the biomedical and scientific fraternities, NIH was ever mindful of the ramifications of such interest. A series of meetings of the Executive Committee for Extramural Affairs was convened with senior staff for the intensive evaluation of the review process at NIH. To no one's surprise, these self-appraisals documented in detail the mechanisms employed and inevitably arrived at the conclusion that, though not perfect, peer review as employed at NIH was the best mechanism for evaluating applications for support of independent research projects yet devised by mankind.

But the grumblings of the discontent and the interest of Congressional investigators would not be easily stilled. And the piercing orb of inquiry soon fixed upon the review mechanism employed by the prestigious National Science Foundation. Here again, by comparison, the NIH system shone as the pristine prototype of scientists passing judgment on the scientific projects of fellow scientists.

Dr. Ronald W. Lamont-Havers recognized the deficiencies of self-appraisal and the dangers inherent in complacency within the system and in July, 1975, established a "Peer Review Study Team" to re-evaluate the peer review system with ample opportunity for input or feed-back from the client community of applicant and/or supported scientists. Senior scientist administrators from the Institutes with significant scientific project grant support programs formed the membership of this team, with the Director of the Institute of General Medical Sciences as Chairman and with a senior scientist administrator experienced in all the grant supported programs as executive secretary. The charge of this stellar group was not only to do an "in-house" evaluation of the review system employed at

NIH but to actively seek and ascertain the feelings, attitudes and possible recommendations for improvement that might be gained from the general public and client communities.

Careful study of the voluminous documentation spanning three decades was followed by the scheduling of "public hearings" in three major regional centers of the U.S. to allow for gathering of information by this group and input or comment by interested persons. Locations and dates of hearings were:

February 12, 1976 - Chicago, Illinois
February 19, 1976 - San Francisco, California
February 26, 1976 - Bethesda, Maryland

With appropriate prior announcement and alerting of the scientific community these meetings were conducted in an atmosphere of scientific fact-finding decorum intent on the gaining of maximum informational input and meaningful recommendations for possible corrective action. Never degenerating into a forum for vituperation, accusation and the venting of spleens, significant constructive comment was recorded although many of the criticisms and suggestions were clearly based on ignorance of the system as currently employed and paucity of substantive information or data to substantiate recommendations for alterations. A report of the suggestions, findings, conclusions, and recommendations of this body will be submitted in June or July, 1976, to the Director of NIH for his consideration in formulating possible changes and/or statement of findings and position of the National Institutes of Health in the evaluation of applications from independent investigators for federal grant support of research projects.

Conclusion: In this scenario of evaluation within the realm of policy formulation in the management of biomedical research, mandated by law for the common weal, but with insufficient or non-existent guidelines for program implementation one becomes spectator to an arena in which the loftiest intent of profession-oriented scientist-administrators sensitive to the needs and omnipresent checks and balances of our pluralistic society have devised a technique for evaluating scientist initiated applications and the awarding of federal support for research efforts directed (even though tangentially) toward the alleviation of suffering of mankind. It is understandable and fitting that the scientific discipline of these administrators would dictate that all requests for project grant support be equally subjected to the full rigor of scientific evaluation by cognizant peers in the subject discipline. It is to this sytem's credit that through the never ending panoply of human interaction, this somewhat amorphous ill-understood procedure has remained responsive to, but not overwhelmed by, the needs of all the participants in this federally funded biomedical research effort and has maintained not only its accountability to executive and legislative branches of the government but also its prestige in the scientific fraternity and to the general public, the taxpayer, to whom it is servitor. And so it is through the conscientious dedication of professional careerists responsive to the continuous pressure from multifarious interests rather than the sporadic eruption of inquisitorial proclamations that policies are most realistically formulated and programs conducted.

Innovation: nurture, serendipity, technology transfer

In many respects the entirety of NIH activities - both intramural and extramural can be interpreted as being dedicated to the "care and feeding of creative minds" or the nurture of scientific innovation. Activities in the intramural laboratories cover a significant spectrum of the interests of their respective supporting institutes. The excellence and productivity of NIH intramural scientists has been addressed in a preceeding section and requires no reiteration here except to indicate the impact of such efforts on other sponsored programs and the web of interaction existing between the various NIH components and their activities.

As discussed in other sections of this presentation the multiplicity and variety of extramural grant supported programs at NIH afford almost unlimited opportunity for the selection of bright young scientists, providing excellent training and experience working with acknowledged, established leaders in the various scientific specialties and the support of independent investigator-initiated research. Maximum innovative freedom is taken for granted by both the investigator and the sponsor so that whatever promising leads may sprout within these fertile brains can be pursued and brought to full fruition. From the standpoint of the independent researcher this provides the best of all possible worlds for creative labor, freedom from monetary and supervisional restrictions, complete control and ownership of data generated, encouragement to publish findings in prestigious journals and personal acclaim by peers and receipt of laurels earned. The sponsoring agency is quite pleased with such arrangements because it permits maximum research effort with minimum staffing for administration and monitoring. The productivity of this rather _laissez faire_ arrangement is attested to not only by the bulk of publications in major scientific journals resulting from NIH grant support but also the dozens of Nobel laureates whose investigations have received NIH support.

Identification of areas of need or programmatic deficits resulting in contracts for research projects has had a stimulating effect on some scientists and perhaps channeled some of their efforts into new endeavors. However, a more productive stratagem consistent with scientific egocentrism and sanctity of originality (in the opinion of the author) has been the utilization of the Request for Applications. After identifying a programmatic need or a potentially contributory concept, institute staff prepare a document explaining the need, the potential utility and the NIH component interested in supporting such efforts. Unlike the Request for Contract Proposals, the RFA has no prescribed protocol provided and relies on the creativeness of the investigator to formulate the total application, with protocol, methodology, budget, etc. for a _grant_. Letters of intent to submit allows the interested institute to indicate to the Division of Research Grants, applications anticipated in response to an RFA, th[illegible] facilitating assignment to the appropriate reviewing group and institute. Upon receipt, these applications are subjected to the peer technical merit review discussed above and grants awarded (without negotiation) in the same manner as the usual application. Combination of the above mechanisms (RFP-contracts, RFA-grants and non-targeted investigator-initiated applications) provides near-optimum utilization of scientific creativity and satisfaction of program needs for innovation and scientific discovery essential for satisfaction of agency goals, responsibilities, and mandates.

The Fogarty International Center, as one of its prime functions, in addition to maintaining intelligence affording currency with foreign scientific activities, sponsors the exchange of scientists between countries. Their visiting scientist program provides the opportunity for renowned foreign scientists to reside on the NIH campus for various periods to prepare manuscripts of their research, learned treatises on their field of specialty and/or to work with colleagues in the intramural laboratories. In addition, there are collaborative programs (U.S.-Japan, U.S.-U.S.S.R.) wherein scientists and administrators from the collaborating countries visit each other, study "the state-of-the-art" and develop mutually beneficial programs for the stimulation of research or improvement of facilities, procedures, technology, and care within selected areas.

Although serendipity has unquestionably contributed to many significant research findings and innovations, its visitation can not be scheduled nor relied upon and remains in the hands of the fates who bestow it meagerly and infrequently. Were scientists to remain in their cloistered cells awaiting such fortuitous occurrences, productivity would certainly be several quanta less. To assist in the transfer of information and technology, each applicant for grant or contract support is required to submit an abstract of the proposed effort. These abstracts with keywords or discriptors indicated are periodically transferred to the Science Information Exchange which maintains computerized records of all current or proposed research projects. Additionally, the National Library of Medicine through its Index Medicus and other recording programs incodes pertinent information from publications in all significant scientific journals. The Medlar facility of NLM makes possible a rapid search and print out of pertinent publications, past and current, on virtually any subject or field of research and even provides copying of selected publications at minimal cost. By combining the services of NLM and SIE, both fed information and material from the intramural and extramural programs, rapid retrieval and exchange of information relative to accomplishments and proposed investigations on a chosen subject or field is facilitated. Thus, duplication of effort and redundancy in research proposals can be minimized and excellence improved by the informed investigator building on previous findings and directing his own investigations into truly original research.

Technology Assessment

Because of the basic and clinical science predominance in all of the programs supported by NIH and the minimal commercial or industrial liaison, this section could more accurately be termed "keeping up with the state of scientific discovery" rather than Technology Assessment and/or Transfer. Although innovations resulting from NIH research projects may eventually find their way into commercial production, this is most often on a limited scale and closely related to the medical application of findings or device development, such as heart-lung machines and dialysis devices. As pursued in this presentation, "Technology Assessment" is on a more individual, personal maintenance of cognizance of new findings and developments within an individual's scientific specialty. Thus re-inventing the wheel is minimized (building the cart is left to industry) and one discovery or innovation serves as the basis or starting point for new research leading (hopefully) to additional new (usually related) discoveries.

Encompassing virtually the totality of disciplines and specialties attributable to biomedical science, the investigational efforts under the aegis of the National Institutes of Health utilize instrumentation, technical innovations and procedures (in short technology) of such scope and diversity as to defy categorization and simplistic assessment. The very survival of an investigator and maintenance of leadership stature or indeed, adequate proficiency and acceptable standing in the scientific fraternity demands not only extensive preparatory training, productive dedication to the discipline, and impressive intellect, but also currency of technological familiarity and proficiency. Such requirements apply equally to scientists supported by grants or contracts as well as their confreres pursuing studies in the intra-mural laboratories of NIH. Although somewhat less rigorous demands are levied on administrators of research programs, they too must maintain a significant level of familiarity with technological and methodological developments in order to effectively dispatch their duties and responsibilities in program surveillance and implementation.

Because of the inclusiveness of scope and ubiquity of technological involvement in virtually all the activities of NIH and the continuity and ever-present evaluation of innumerable technological advances, "the assessment of technology" tends to lose its identity as a clearly defined procedure and melds into the day-to-day pursuit of scientific excellence and achievement. Thus technology in all its forms is under constant assessment and is not clearly defined nor restricted to a few closely related disciplines.

Consistent with their espoused role as "scientists in good standing," intramural investigators at NIH zealously maintain membership in the requisite learned professional societies and assiduously pour over the publications of these august bodies to remain "at the forefront" of knowledge and findings in their chosen field of endeavor. Professional acquaintances and frequent interaction with peers on a personal basis is jealously maintained. Frequent attendance at major scientific conventions is unquestioned and every opportunity is seized to present and hear presentations of latest discoveries and developments in the forums thus provided. There is, among this group of NIH employees, an overpowering compulsion (encouraged by the organizational hierarchy) to share discoveries and findings with others of similar leanings through publication in the multitude of scientific journals. Reciprocal visits to academic, independent and commercial laboratories both in the United States and abroad have become commonplace and exchanged periods of residency and work in laboratories of peers in the same field has become an accepted way of life. The laboratory or investigators that cleave to their own studies without extending invitation to confreres or making pilgrimage to the laboratories of acknowledged leaders or "centers of excellence" soon are numbered in the van of less than first rate.

Investigators conducting efforts supported by grants or contracts from NIH form the bulk of the membership of the biomedical science fraternity, subscribing to all its requirements and enjoying its concomitant privileges and laurels. Predominant technology in one's field is assessed and currency maintained on an individual basis by this group in much the same manner as described above for the intramural staff of NIH for they are siblings in the same disciplinary family. The scientist-administrator employed by NIH for the conduct of evaluation and administration of supported research is a different kind of animal with different allegiancies and responsibilities. Even though divorced from the bench and more deeply involved with bookkeeping and documentation of actions, these individuals exert significant force in the direction and coordination of research within their assigned areas of responsibility. Through their surveillance of individual programs they are often among the first to be apprised of new findings or innovations in programs for which they are responsible. With their broader overall view of many investigations in a given area they are able to serve as agents for liaison and coordination of information exchange between: 1) investigators within the field, 2) between investigators and the senior staff of the granting institution(s) and their advisory councils through periodic reports.

Although at first blush, the primary responsibility of the disciplinary study section and other initial merit review groups would appear to be review of applications for support, these bodies are prime factors in assessment and updating of technology in the fields they represent. By definition consistently borneout in practice, these groups are constituted of recognized leaders and senior statesmen in their respective disciplines. Each group is convened three times each year, affording continual familiarization and appraisal of technological developments and innovations in their fields. Thus all applications for support of studies are evaluated against constantly updated yardsticks of technological sophistication and validity. In a mutually beneficient interaction the best versed or technological innovators become successful recipients of support to further their studies and the unsuccessful have access to critiques of their proposals, revealing both strengths and deficits which can serve as an effective guide to improvement of technological competence.

The Advisory Councils of the various bureaus, institutes and divisions at NIH are responsible for advising appropriate officials concerning policy formulation and program development and/or guidance, new initiatives etc. These bodies meet three or four times annually and at each meeting are subjected to briefings in which staff of various organizational units present program developments, accomplishments, technological innovations, applications, significant accomplishments and/or areas of need (lacunae). Through such interactions, emphasis and support have been channeled into initiatives in a wide range of technological development, i.e., heart assist devices, renal dialysis, diagnostic instrumentation and methodologies, purification or separation of biological agents, etc. Far from being viewed as the enemy, private industry involved in development of scientific technology and instrumentation is cherished by NIH as an indispensable handmaiden in the support of and pursuit of scientific achievement. Periodically, by invitation, individual firms or groups of firms are provided opportunity, facilities and necessary publicity for formal presentations, informal discussions and demonstrations of new instrumentation and technical methodologies. "Trial periods" or employment of new technology in NIH laboratories (often with an industry representative as on-the-job instructor) is a common sequel to such presentations.

Completing this absolutely informal but rigorously pursued cycle of continuous input, appraisal, employment and updating of technology, periodic seminars, symposia, workshops, and conferences are sponsored by NIH to evaluate and report on "the state of the art" in a particular subject or discipline. Conducted with the all-pervading aura of "scientificity" these colloquia are usually chaired by the acknowledged guru of the discipline or at least a chosen disciple with all necessary logistic and administrative support provided by dedicated staff. Such chautauquas are convened, often distant from NIH, in surroundings calculated to be most conducive to mentation and the most prolific of scientific discourse. In true scientific elitist tradition, stellar achievers present "papers" describing in infinite detail their most recent contribution to the fund of pertinent knowledge to the enthralled audience of eager peers (or near peers) including the intramural scientists and extramural scientist-administrators from NIH. Although a given symposium usually deals with a selected investigational area, the multiplicity of topics covered each year taxes the imagination, ranging from alimentary absorption, biomedical engineering, chemotherapy, hemostasis, immunology, nuclear medicine, to xenon arc retinal coagulation, etc.

Regulatory Process at NIH .

Unlike agencies such as the Food and Drug Administration or the Agriculture Department, NIH has no licensing authority nor function, nor does it regulate prices or the delivery of goods or services. Additionally, the aura of professional altruism and benevolent patronage of science coupled with the laissez faire largesse attributed to its support of biomedical research for the common weal appear inconsistent if not incompatible with the concept of regulation or the role of enforcer. Nevertheless, no aspect of life including the nether world of benign bureaucracy is immune from strictures and regulations designed to insure collective security or protection with (hopefully) minimum violation of individual freedom and scientific liberty. Within this context fall a splendid array of considerations. Scientific investigations must be conducted according to approved protocols. Study subjects, whether human or animal, must not be subjected to unnecessary hazard, injury, pain or mental anguish. Individual privacy and confidentiality of personal information and research data must be protected. Public funds expended in the furtherance of investigations must be disbursed equitably, must not be spent in a capricious or arbitrary manner and fiscal accountability must be maintained. And so, as the list of items requiring control or regulation grows in length and complexity it would appear that a similarly complex and lengthy specification of regulatory measures would be developed.

Rather than the post facto imposition of penalties for violations, NIH has developed a highly successful means of insuring compliance to regulations simply by withholding funds until satisfaction and documentation is obtained. In the case of research projects conducted in its own laboratories, adherence to protocol is insured by the lines of authority and accountability rising through supervisory strata ending in the Office of the Deputy Director for Science, NIH. Expenditures of funds are carefully monitored by supervisors with each branch limited to the amount of its own designated budget and central account. A special committee composed of researchers, physicians, clergy and general public representatives must review and approve as free of potential hazard any project utilizing human subjects (regardless of how superficial the involvement or benign the procedures) before that project may be initiated. Animal studies must similarly be reviewed and determined to comply with guidelines for humane care of such animals, maintenance of sanitary, optimal living environment and the avoidance of unnecessary pain, stress or anguish to the animal (regardless of species). If all the above criteria are not satisfied, the study may not be conducted.

Relationships between NIH and investigators supported by grants and contracts is perhaps more remote but no less restrictive. By definition such awards are made to the university or sponsoring institution on behalf of the principal investigator for the conduct of investigations as described in the reviewed and approved protocol. Thus the sponsoring institution is placed as a buffer between the supplicant and the funding agency. In this manner, human and animal research subject committees similar to the description above must be established at each applicant institution and must review and approve applications prior to review by the initial merit review committee at NIH. Documentation of this review and resolution of reservations or questions must be received by NIH before funding of the program.

A significant amount of discretion is vested in the grantee institution for expenditure of funds within the guidelines of the award. However, certain restrictions may be imposed, are clearly described on the award statement and require review and approval by NIH (usually the program officer) before authorization can be given. Under all circumstances the grantee institution is still subject to GAO audit and disallowance of inappropriate expenditures. All of the restrictions, policies, and procedures to which awardees are subjected are clearly enumerated in Policies and Procedures Guidelines provided routinely and updated periodically for all awardees.

All supported programs are required to submit progress and expenditure reports no less frequently than annually. Those programs enjoying more than one year of committed support must also submit applications annually for the next year of committed funds with discussion and description of efforts to be pursued during each period. This documentation must be reviewed by the responsible scientist-administrator (program officer) at NIH and found to be compatible with acceptable productivity or contribution and consistent with the original approved protocol before an award can be made. Although commitment may extend for up to five years, funds are actually awarded on a year-by-year basis. The above description is based on grant requirements but is also applicable to contract programs which have the additional requirement for a contract specialist to oversee the legal obligations inherent in contractual agreements.

Whereas patentable discoveries may be negotiable under a contract, such negotiations are conducted and agreement reached as to whom shall be patent recipient prior to award. Grant programs, with rare exceptions, require that any patentable discovery made during the period of such grant must be released by the grantee for public use patent by the federal government. Documentation of such agreement is required before each award. Without belabouring detailed requirements, it appears that NIH has, through its extensive relationships with recipients of awards for the support of a wide variety of programs of research, training and other activities designed for the increased productivity of biomedical research, developed highly effective mechanisms for surveillance of federally funded programs under its responsibility. It has also perfected a system of checks and balances yielding an exceptional level of compliance with guidelines and directives. Annual program review enforces adherence to approved protocols. The system works smoothly with only rare recourse to the agony of GAO audit with the possibility of disallowance of fund expenditure. Thus the professional ego and appetites of both the supplicant and benefactor can be maintained with NIH retaining the façade of philanthropic patron of the biomedical sciences while keeping an iron hand on the purse strings. This appears to be a significant if not unique example of the effectiveness of gentle persuasion with a coercive club, as opposed to brute force and police action.

Political-Institutional Relationships

The National Institutes of Health, although identified as an administrative unit within the Department of Health, Education, and Welfare, as discussed in a previous section of this paper, represents a paradoxical anomaly probably unique in the federal bureaucracy. This amorphous conglomeration of semi-autonomous bureaus, institutes and divisions has no single spokesman nor coherently organized supporting interest group. The Director of the National Institutes of Health, though the titular head of this disparate aggregation of categorical components, is in actuality an overseer of policy, administrative consistency, and adherence to legislative and departmental directives and guidelines.

Organizational autonomy may be enjoyed only at the cost of individual accountability and self support. Therefore each categorical unit is supported by and must continually curry favor of a wide spectrum of special interest groups, some with obvious interests and ties but others with somewhat obscure, tenuous or tangential interests. The listing of all such groups would comprise the membership of virtually every scientific, medical, or administrative organization in the United States with any involvement or interest in biomedical research, service or education. The very nature of such supporting groups being national and international in membership, interest, and influence tends to elevate NIH programs above local or state provincialism. The regionalism imposed on other agencies within the executive departments is of little concern in the conduct of most of NIH sponsored efforts. State sovereignty and congressional prerogatives and power cannot be taken lightly and each year the director and support staff of each unit of NIH are required to appear before both House and Senate appropriations committees to defend their own budget requests, report on activities, accomplishments and needs and respond to any inquisitorial attack from the representatives of Congressional constituants. This annual "time on the rack" has resulted in a high level of political competence and administrative strength, accountability, and program surveillance in each of the units which is coordinated into a strong supportive cadre for the functions of the Office of the Director, NIH.

With the above universality of interest group support and the effective mechanisms for making awards directly to recipient institutions without going through state or local governmental agencies, supported programs can be expeditiously and efficiently funded and recognition for largesse directly enjoyed by NIH. However, consonant with the value of congressional friendship, NIH policy dictates that no award may be made until 48-72 hours after notification of appropriate Congressional (including Senate) representatives of an impending award. This lead time allows senators and representatives to make public announcement ("of their accomplishments") to their constituencies, if they desire, prior to the actual receipt of the award or other public announcement.

Input, questions, complaints etc. from constituents to legislators are often referred to NIH and through the Office of Congressional Liaison to the appropriate organizational unit with immediate (often within 24 hours and seldom more than 72 hours after receipt) response to the concerned congressional office with appropriate material for response to the original constituent. Such inquiries are handled courteously, factually, and expeditiously as a matter of course but do not appreciably effect operational procedures of the units. Congressional endorsement of an application is acknowledged but routinely disregarded in the merit review of an application or subsequent award. Discreet attention is usually paid, however, to expressed congressional interest in the administration of a grant or contract supported program.

Compliance by recipients of awards with federal regulations (i.e., human rights, non-discrimination, etc.) and NIH policies and program guidelines (i.e., human and animal research, equipment accountability, fiscal and managerial policies) must be documented satisfactorily prior to award issuance. If such compliance runs counter to local or state policy, negotiation and reconciliation of incompatibilities remains the responsibility of the award recipient institution or organization. Enforcement of compliance is discussed in the section on Regulatory Process.

Resource Management: Manpower

The management, evaluation and development of manpower within the intramural programs of NIH has been adequately treated in that separate section but is not entirely unrelated to extramural activities in this area, as shall be seen. Staff within the components of NIH perform a wide array of review, fiscal, budget, management and administrative tasks directly supportive of scientific research but clearly distinct from "bench investigations." Simplistic categorization of staff reveals the expected support and clerical, budget and accounting, grants and contract management, and scientific administrators. All of these groups are neatly accommodated into the various series and grade level structures compatible with their status as civil service employees. In practically all series or functions there appears to be an entry, journeyman, and dead-end level. Despite the CSC merit promotion system, the steepness of the pyramid at the top and partisanship at the upper levels makes this progress most dramatic and painful in the ranks of health scientists administrators who often "dead-end" at GS-14 and rarely progress beyond GS-15 levels.

Nonetheless, early in the 1960's NIH initiated a Grants Associate Program to which selected candidates (almost invariably with doctoral degrees) were afforded a year of internship under the guidance of a senior preceptor to familiarize themselves with all the programs of NIH and, hopefully, to produce a cadre of highly competent administrators of scientific programs. Each candidate is given short term assignments in different institutes and managerial, review or evaluative processes in an on-the-job familiarization with such activities. Concomitantly, periodic seminars are attended providing elucidation of organizational structures, relationships, policies and functions. After a year of such training, the grant associate is free to accept assignment for full time employment from among available openings. Unlike the intramural research associate, in this program few are culled and most progress rapidly because of increased familiarity with the system and visibility afforded by their diverse assignments. The competence of alumni has usually been acceptable or better but not necessarily greater than their less favored confreres who have been "direct hire" and come up through the ranks through considerably longer service and greater experience.

Perhaps among the most dramatic impacts and stimuli for the development of manpower and excellence of their achievements in biomedical science have resulted from the many support programs of NIH discussed in an earlier section. In addition to already established mechanisms, new programs are frequently established to satisfy newly perceived needs for manpower development. Each of the components of NIH, at a variety of levels, periodically conducts (usually through contracted services of outside consultants) surveys of personnel and activities currently available, in the training pipeline, facilities for training or development and the manpower or research needs within special interest areas. Upon evaluation of collected data and recommendations of advisory groups, special guidelines, procedures and procedures and program mechanisms are promulgated to alleviate the perceived need. Two such programs are described under Appendix E. General Research Support formula grants to institutions of higher education provide these grantees the opportunity for discretionary selection and support of initial research efforts of neophyte investigators who subsequently compete favorably for research grant support as principal investigators. Through the many mechanisms discussed above, NIH contributes dramatically to the development of manpower and excellence of the general fields of biomedical science but also directs significant impetus to the development of personnel and research in specific designated fields, disciplines, categorical diseases, or ethnic populations.

Information

A major portion of information management has been covered under sections dealing with innovation and technology assessment. A review of the discussions of contracts, grants and peer review further allude to the incoding of pertinent information from applications and awards in the computerized IMPAC system. Various record and file types are utilized in this system with necessary hardware and software, sophisticated chaining, linking, analysis etc. to serve the many demands for information retrieval at NIH. The Division of Computer Research and Technology provides the technical competence and facilities with multiple back up for the newest, more advanced IBM 360 computers necessary to service these needs. Numerous input-output terminals are located throughout the B/I/D's and even at remote locations providing facilities for special program or data input to satisfy requirements of individual users. Fiscal and accounting data, program content information and even text editing competence (WYLBUR) and analytical and computational services are provided, utilizing all the major computer languages and program library facilities for rapid (usually 24-hour or less) response to queries, as well as on-line and time sharing capabilities. Most B/I/D's within their program planning and analysis sections employ competent personnel to maintain and up-date their own documentation and to interface with both the IMPAC and DCRT systems, records, and facilities.

Property

There is little need to indulge in excessive discourse on the procedures for acquiring, accounting for, and disposing of furniture, clerical machinery or even research laboratory equipment within the confines of NIH. Procedures are those normally followed in governmental agencies. Of greater interest, perhaps, would be the disposition of property acquired with grant or contract funds, providing a final curtsy for NIH as patron of biomedical science.

Upon submission of a grant or contract application, equipment needs of all sorts are clearly indicated and justified by the applicant. Upon approval and award, such property may then be acquired with awarded funds. Although technically ownership of such items resides with NIH and accountability is required of the awardee, title to such property is usually given to the awardee institution at the termination of a grant or contract program. Rarely, if ever, is any equipment or material returned to NIH upon termination of such programs. In the event that an investigator wishes to transfer his activities to an institution other than the original awardee, procedures are available for equipment transfer to the new institution simply by its relinquishment by the first and acceptance by the second institution. In many cases crating, shipment, and set-up costs are paid from grant funds on the theory that all this is essential for the conduct of desired (and previously approved) research.

Construction authority for erection of facilities is limited at NIH and restricted to certain special programs. Alteration and renovation of existing facilities may be funded on most programs as deemed appropriate for the conduct of the approved program. Limitations are placed on an amount ($75,000 maximum) to be spent and acceptable items to be paid for. Under these restrictions, line drawings, descriptions and itemized costs must be reviewed and approved by the funding agency. No items considered to be construction, i.e., weight bearing walls, ramps, extensions, etc., can be funded as alteration and renovation. However, when the work has been completed and the bills paid, the grantee institution remains owner of the renovated facility.

Summary

It is with great timidity that one approaches the summarization of this presentation. To the author, the challenge is not unlike that of encapsulating in a few paragraphs the entire contents of the books of Genesis and Revelations combined. Each section of this compilation is, in effect, a condensation of numerous documents dealing with the subject under consideration. Of necessity, much of the preceding documentation has been more narrative than evaluative of the material covered. In other sections critique or evaluation has been included in the overall treatment. The intimacy of involvement of the author in many of the program operations may have slanted the presentation but it is hoped that objectivity has been maintained in spite of the author's propensity for verbal imagery and hyperbole.

The National Institutes of Health, originating as a hospital service for sick and injured merchant seamen has evolved through the years, in direct response to health needs of the Nation, to make real contributions in the control of infectious diseases and enlargement of medical services available in its own facilities. Laboratory research in biomedical science has been a most significant component of this agency's activities. Legislative authorization and increased availability of funds in 1944 led to an exponential increase in research activities in its own laboratories, but an even greater augmentation of grant and contract support of research and training efforts in virtually all disciplines related to biomedicine has resulted in NIH currently enjoying unquestioned leadership in the support of biomedical excellence.

Excellence has certainly been achieved in the research laboratories of NIH and the philosophy developed there led to the utilization of a unique "peer review system" to evaluate applications to determine the recipients of grant and contract awards. This system has been criticized but has weathered the storm of complaints from unsuccessful supplicants and still remains the most effective method for evaluating investigator initiated proposals yet devised. The productivity of such evaluation and support is attested to by the dozens of Nobel laureates whose investigations have been funded through this mechanism. Research advances and innovations resulting from such investigations have accrued immeasurably to the benefit of mankind, not the U.S. alone.

Because of the mental set of NIH staff, awardees, and alumni, technology assessment and transfer is interpreted quite narrowly as "research findings serving as foundation for new research efforts" rather than the usual concept of innovation of technology - through development and commercial application leading to delivery of a product for a new consumer usage. With no licensing, enforcement or audit authority, compliance with appropriate regulations, policies and program requirements is obtained by NIH through required documentation prior to award rather than post facto punishment. By making awards directly to applicant institutions, interaction with state and local governmental entities is minimal. On the other hand, requirements placed on it for budget defense and numerous Congressional hearings, involves senior NIH staff frequently and conspicuously in the federal political arena.

Despite the many frustrations of management staff, NIH has taken a significant leading role in recognizing the need for excellence in the specialty of "the Scientist Administrator" and instituting training programs for formalized and on-the-job training to increase the proficiency of staff members in this activity. Even more important to the achievement of scientific excellence and the development of superior scientific talent is the continuing evaluation of manpower needs in the various biomedical disciplines and the modification or development of programs to help fill the identified demand for highly qualified, competent biomedical scientists. Of significance to this presentation is the constantly evolving and changing nature of NIH programs and relationships, building on previous experience and accomplishments, in constant pursuit of excellence and contributing to satisfaction of the biomedical research needs of mankind.

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APPENDIX A

Legislative Chronology

Appendix A

LEGISLATIVE CHRONOLOGY

This legislative chronology is limited to enactments that had a major influence upon the Marine Hospital Service as it evolved into the Public Health Service, to legislation leading to the establishment of the National Institutes of Health, and to specific NIH legislation with the exception of appropriations bills.

July 16, 1798—"An Act for the relief of sick and disabled Seamen" established the Marine Hospital Service for merchant seamen. The Marine Hospital Service—forerunner of the present-day Public Health Service—became a component of the Treasury Department. A monthly hospital tax of 20 cents was deducted from the pay of merchant seamen in the first prepaid medical care plan in the United States. (Stat. L. 604.)

March 2, 1799—An amending act to the legislation of 1798 extended Marine Hospital Service benefits to officers and men of the U.S. Navy. This arrangement continued until 1818 when the Navy built its own hospitals. However, the deduction of 20 cents per month from the pay of Navy and Marine Corps personnel continued until June 15, 1943. (1 Stat. L. 729.)

June 29, 1870—A bill to reorganize the Marine Hospital Service and establish a central controlling office in Washington, D.C., was enacted. This act also increased the amount of hospital tax paid by seamen from 20 cents to 40 cents per month, a tax which continued until 1884. (16 Stat. L. 169.)

(After the seaman's hospital tax was abolished July 1, 1884, the cost of maintaining Marine hospitals was paid out of a tonnage tax until 1906. Since then medical care for merchant seamen and other beneficiaries of the Service has been supported by direct congressional appropriations.)

March 3, 1875—An Act was passed authorizing the admission of seamen from the Navy and other Government services to Marine hospitals on a reimbursable basis. (18 Stat. L. 377.)

April 29, 1878—The first Federal Quarantine Act "to prevent the introduction of contagious or infectious diseases into the United States" was passed. (20 Stat. L. 37.)

January 4, 1889—A bill to establish a commissioned officer corps in the Marine Hospital Service was passed. This law established a mobile corps subject to duty anywhere upon assignment, a policy that had been in effect since Dr. Woodworth, assumed leadership of the Marine Hospital Service in 1871. (25 Stat. L. 639.)

March 27, 1890—Congress gave the Marine Hospital Service interstate quarantine authority. (26 Stat. L. 31.)

February 15, 1893—A new Quarantine Act was passed, following outbreaks of cholera in Europe, strengthening the inadequate Quarantine Act of 1878 by giving the Federal Government the right of quarantine inspection. (27 Stat. L. 449.)

March 2, 1899—The Marine Hospital Service was directed by Congress to investigate leprosy in the United States. (30 Stat. L. 976.)

July 1, 1902—A bill to increase the efficiency and change the name of the Marine Hospital Service to Public Health and Marine Hospital Service was enacted. The law authorized the establishment of specified administrative divisions, and, for the first time, designated a bureau of the Federal Government as an agency in which public health matters could be coordinated. (32 Stat. L. 712.)

Another law, usually referred to as the Biologics Control Act, authorized the Public Health and Marine Hospital Service to regulate the transportation or sale for human use of viruses, serums, vaccines, antitoxins, and analogous products in interstate traffic or from any foreign country into the United States. (P.L. 57-244, 32 Stat. L. 728.)

August 14, 1912—Under an act, the name Public Health and Marine Hospital Service was changed to Public Health Service. The legislation also authorized the Public Health Service to conduct field investigations and studies and, in particular, investigations of the diseases of man and pollution of navigable streams. (37 Stat. L. 309.)

July 9, 1918—The Chamberlain-Kahn Act provided for the study of venereal diseases by the Public Health Service (40 Stat. L. 886.)

October 27, 1918—An act establishing a Reserve Corps for the Public Health Service was passed. The 1918 influenza pandemic emphasized the need for a reserve corps in the Service to meet such emergency situations. (40 Stat. L. 1017.)

January 19, 1929—The Narcotics Control Act provided for construction of two hospitals for the care and treatment of drug addicts, and authorized creation of a Narcotics Division in the Office of the Surgeon General of the Public Health Service. (P.L. 70-672, 45 Stat. L. 1085.)

April 9, 1930—A law changed the name of the Advisory Board for the Hygienic Laboratory to the National Advisory Health Council (P.L. 71-106, 46 Stat. L. 152.)

May 26, 1930—The Ransdell Act reorganized, expanded, and redesignated the Hygienic Laboratory as the National Institute of Health. The act authorized $750,000 for the construction of two buildings for NIH and authorized the establishment of a system of fellowships. (P.L. 71-251, 46 Stat. L. 379.)

June 14, 1930—A law authorized creation of a separate Bureau of Narcotics in the Treasury Department to control trading in and use of narcotic drugs for therapeutic purposes. Also, the legislation changed the Narcotics Division of the Public Health Service to the Division of Mental Hygiene, giving the Surgeon General authority to investigate the causes, treatment, and prevention of mental and nervous diseases. (P.L. 71-357, 46 Stat. L. 585.)

August 14, 1935—The Social Security Act was an event of major importance in the progress of public health in the United States. This act authorized health grants to the States on the principle that the most effective way to prevent the interstate spread of disease is to improve State and local public health programs. With this legislation, the Public Health Service became adviser and practical assistant to State and local health services. (P.L. 74-271, 49 Stat. L. 634.)

August 5, 1937—A law established the National Cancer Institute to conduct and support research relating to the cause, diagnosis, and treatment of cancer. The law authorized the Surgeon General to make grants-in-aid for research projects in the field of cancer, provide fellowships, train personnel, and assist the States in their efforts toward cancer prevention and control. (P.L. 75-244, 50 Stat. (L. 559.)

April 3, 1939—The Reorganization Act of 1939 transferred the Public Health Service from the U.S. Treasuray Department to the Federal Security Agency. (P.L. 76-19, 53 Stat. L. 561.)

July 1, 1944—The Public Health Service Act consolidated and revised laws pertaining to the Public Health Service and divided the Service into the Office of the Surgeon General, Bureau of Medical Services, Bureau of State Services, and the National Institute of Health. The act gave the Surgeon General broad powers to conduct and support research into the diseases and disabilities of man, authorized projects and fellowships, and made the National Cancer Institute a division of NIH. The act also empowered the Surgeon General to treat at Public Health Service medical facilities, for purposes of study, persons not otherwise eligible for such treatment. (P.L. 78-410, 58 Stat. L. 682.) Under this provision, the Clinical Center was later established.

July 3, 1946—The National Mental Health Act was designed to improve the mental health of U.S. citizens through research into the causes, diagnosis, and treatment of psychiatric disorders. It authorized the Surgeon General to support research, training, and assistance to State mental health programs. (P.L. 79-487, 60 Stat. L. 421.) (The National Institute of Mental Health was established under the authority of this law on April 1, 1949.)

August 13, 1946—The Hospital Survey and Construction Act (Hill-Burton Act) authorized grants to the States for construction of hospitals and public health c

centers, for planning construction of additional facilities, and for surveying existing hospitals and other facilities. (P.L. 79-725, 60 Stat. L. 1040.)

June 16, 1948—The National Heart Act authorized the National Heart Institute to conduct, assist, and foster research; provide training; and assist the States in the prevention, diagnosis, and treatment of heart diseases. In addition, the act changed the name of National *Institute* of Health to National *Institutes* of Health. (P.L. 80-655, 62 Stat. L. 464.)

June 24, 1948—The National Dental Research Act authorized the National Institute of Dental Research to conduct, assist, and foster dental research; provide training; and cooperate with the States in the prevention and control of dental diseases. (P.L. 80-755, 62 Stat. L. 598.)

August 15, 1950—The Omnibus Medical Research Act authorized the Surgeon General to establish the National Institute of Neurological Diseases and Blindness, as well as additional institutes, to conduct and support research and research training relating to other diseases and groups of diseases. (P.L. 81-692, 64 Stat. L. 443.) (The National Institute of Arthritis and Metabolic Diseases and the National Institute of Neurological Diseases and Blindness were established under the authority of this act on November 22, 1950. Under this same act, the National Institute of Allergy and Infectious Diseases was established on December 29, 1955, replacing the National Microbiological Institute which was originally established November 1, 1948, under authority of section 202 of the Public Health Service Act.)

July 28, 1955—The Mental Health Study Act authorized the Surgeon General to award grants to nongovernmental organizations for partial support of a nationwide study and reevaluation of the problems of mental illness. Under this act, the Joint Committee on Mental Illness and Health was awarded grant support for 3 years. (P.L. 84-182, 69 Stat. L. 381.)

July 3, 1956—The National Health Survey Act authorized the Surgeon General to survey sickness and disabilities in the United States on a sampling basis. (P.L. 84-652, 70 Stat. L. 489.)

July 28, 1956—The Alaska Mental Health Enabling Act provided for territorial treatment facilities to eliminate the need to transport the mentally ill outside Alaska. It also authorized Public Health Service grants to Alaska for its mental health program. (P.L. 84-830, 70 Stat. L. 709.)

July 30, 1956—The Health Research Facilities Act of 1956 authorized a Public Health Service program of Federal matching grants to public and nonprofit institutions for the construction of health research facilities. (P.L. 84-835, 70 Stat. L. 717.)

August 2, 1956—The Health Amendments Act of 1956 authorized the Surgeon General to assist in increasing the number of adequately trained nurses and professional public health personnel. It also authorized Public Health Service grants to support the development of improved methods of care and treatment of the mentally ill. (P.L. 84-911, 70 Stat. L. 923.)

August 3, 1956—An amendment to Title III of the Public Health Service Act, the National Library of Medicine Act, placed the Armed Forces Medical Library under the Public Health Service, and renamed it the National Library of Medicine. (P.L. 84-941.)

July 12, 1960—Recognizing the importance of cooperation in international health research, Congress passed the International Health Research Act. Under the new law the Surgeon General was authorized to establish and make grants for fellowships in the United States and participating foreign countries; make grants or loans of equipment and other materials to participating foreign countries for use by public or nonprofit institutions and agencies; participate in international health meetings, conferences, and other activities; and facilitate the interchange of research scientists and experts between the United States and participating foreign countries. (P.L. 86-610, 74 Stat. L. 364.)

September 15, 1960—A law amended the Public Health Service Act to authorize grants-in-aid to universities, hospitals, laboratories, and other public and nonprofit institutions, and to strengthen their programs of research and research training in the sciences related to health. The act also authorized the use of funds appropriated for research or research training to be set aside by the Surgeon General in a special account for General Research Support grants. (P.L. 86-798, 74 Stat. L. 1053.)

October 17, 1962—An act authorized the Surgeon General to establish the National Institute of General Medical Sciences and the National Institute of Child Health and Human Development. The latter was authorized to conduct and support research and training relating to maternal health; child health; human development, in particular the special health problems of mothers and children; and the basic sciences relating to the processes of human growth and development. The former was authorized to conduct and support research in the basic medical sciences and related behavioral sciences which have significance for two or more institutes, or which are outside the general area of responsibility of any other institute. (P.L. 87-838, 76 Stat. L. 1072.) (On January 30, 1963, the National Institute of Child Health and Human Development and the National Institute of General Medical Sciences were established under this act.)

September 24, 1963—A law amended the Health Research Facilities Act of 1956 (Title VII to the Public Health Service Act) to allow grants for multipurpose facilities that would provide teaching space as well as essential research space. (P.L. 88-129, 77 Stat. L. 164.)

October 24, 1963—The Maternal and Child Health and Mental Retardation Planning Amendments of 1963 amended the Social Security Act of 1935 by authorizing a five-point grant program of $265 million, over a 5-year period. Major provisions designed to prevent mental retardation, included increased Federal grants for maternal and child health services and crippled children's service administered by the Children's Bureau; a new 5-year program of grants to the States for health care of expectant mothers who have, or are likely to have, conditions associated with childbearing which may lead to mental retardation; funds for research to improve maternal and child health and crippled children's services; and grants to the States to assist in developing plans for comprehensive State and community programs to combat mental retardation. (P.L. 88-156, 77 Stat. L. 273.)

October 31, 1963—A companion measure to Public Law 88-156 was the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963. This act authorized a total of $329 million over a 5-year period for grants to assist the construction of mental retardation research centers and community mental health centers, and to train teachers of mentally retarded and other handicapped children. (P.L. 88-164, 77 Stat. L. 282.)

August 18, 1964—The Hospital and Medical Facilities Amendments of 1964 extended the Hospital Survey and Construction Act of 1946 (Hill-Burton Act) for 5 years with a total authorization of $1.4 billion. (P.L. 88-443, 78 Stat. L. 447.)

August 27, 1964—The Graduate Public Health Training Amendments of 1964 extended the authorization for public health traineeships and training grants to schools of public health, nursing, and engineering for 5 years, through June 30, 1969. (P.L. 88-497, 78 Stat. L. 613.)

August 4, 1965—The Mental Retardation Facilities and Community Mental Health Centers Construction Act Amendments of 1965 provided monies through Fiscal Year 1972 to help finance initial staffing of community mental health centers which were authorized in the original act; extended and increased appropriations authority for mental retardation education research and demonstration projects; and authorized increased annual funds through Fiscal Year 1969 for training teachers of the handicapped young. (P.L. 89-105.)

August 9, 1965—The Health Research Facilities Amendments of 1965 extended the program for construction of health research facilities for 3 years with $280 million authorized for that period in lieu of the previous $50 million annual appropriations authorizations. (P.L. 89-115.)

August 31, 1965—A supplemental appropriations act resulting from recommendations of the President's Commission on Heart Disease, Cancer and Stroke provided an additional $20,250,000 (shared by NCI, NHI, NIGMS and NINDB) to intensify and expand support of research in the three major "killer" diseases. (P.L. 89-156.)

October 6, 1965—The Heart Disease, Cancer and Stroke Amendments of 1965 provided for establishment of regional programs of cooperation in research, training, continuing education and demonstration activities in patient care among medical schools, clinical research institutions and hospitals so that the latest treatment methods for the three diseases may be more widely available to patients. (P.L. 89-239.)

October 22, 1965—The Medical Library Assistance Act was passed, authorizing the National Library of Medicine's Extramural Programs. (P.L. 89-291.)

August 3, 1968—A law authorized the designation of a national center for biomedical communications as the Lister Hill National Center for Biomedical Communications. (P.L. 90-456.)

August 16, 1968—Public Law 90-489 amended the Public Health Service Act by authorizing the Secretary to establish a National Eye Institute and to change NINDB to the "National Institute of Neurological Diseases." The bill was passed by the House on August 1 and by the Senate, August 2; President Johnson approved the bill August 16. The new Institute was formed from NINDB's programs to conduct and support research for new treatment and cures, and training relating to blinding eye diseases and visual disorders.

Health Manpower Act of 1968 (P.L. 90-490), extended and expanded the following five health laws then in effect: Health Professions Educational Assistance Act of 1963, as amended; Nurse Training Act of 1964, as amended; Allied Health Professions Personnel Training Act of 1966; Health Research Facilities Act of 1956, as amended, and Public Health Service Act of 1944, as amended. The measure provided a two-year extension, through FY 1971, of the above legislation with the exception of the Allied Health Professions Act which was extended only through FY 1970.

October 24, 1968—President Johnson signed legislation (P.L. 90-636) further amending the name of the parent organization (NIND) to National Institute of Neurological Diseases and Stroke.

March 12, 1970—Public Law 91-208 (84 Stat. 52), an amendment to the Public Health Service Act, extended for an additional period of time and made coterminous through June 30, 1973, the authority to make formula grants to schools of public health, project grants for graduate training in public health, and traineeships for professional public health personnel.

March 13, 1970—The Medical Library Assistance Extension Act of 1970 (P.L. 91-212; 84 Stat. 63) amended the Public Health Service Act to improve and extend the provisions relating to assistance to medical libraries and related instrumentalities for 3 years through June 30, 1973.

October 30, 1970—P.L. 91-515 amended the PHS Act to provide: (1) Extension of research contract authority in areas of public health through June 30, 1974; (2) Authorization of mission-related clinical training (as well as research training) by the National Institute of General Medical Sciences; (3) Clarification of terms in the regulation of biological products; (4) Clarifying and technical directives relating to appointment, compensation and functions of advisory councils and committees, and (5) Extension of statutory authority for Regional Medical Programs, Comprehensive Medical Planning, and Health Services Research and Development.

November 2, 1970—The Health Training Improvement Act of 1970 (P.L. 91-519) extended and amended allied health professions training authority (which expired June 30, 1970) and established eligibility of new Health Professions Educational Assistance Schools for "start-up" grants.

December 24, 1970—The Congress enacted the Family Planning Services and Population Research Act of 1970 (P.L. 91-572) to expand, improve and better coordinate family planning services and population research activities of the Federal Government.

May 22, 1971—Congress passed into law the Supplemental Appropriations Bill (P.L. 92-18) which included $100 million for cancer research. This appropriation was made in response to the President's State of the Union Address in which he called for "an intensive campaign to find a cure for cancer." The appropriation includes authority under grants and contracts, as well as direct construction authority for the National Cancer Institute.

July 9, 1971—P.L. 92-52 amended the Public Health Service Act to provide for extension of student loan scholarship programs for up to four fiscal years.

November 18, 1971—The President signed the Comprehensive Health Manpower Training Act of 1971 (P.L. 92-157) to provide increased manpower in the health professions, and the Nurse Training Act of 1971 (P.L. 92-158) to provide training for increased numbers of nurses.

December 23, 1971—P.L. 92-218, the National Cancer Act of 1971, enlarged the authorities of the National Cancer Institute and the National Institutes of Health in order to advance the national effort against cancer. The authority of the Director, NCI, was expanded, a National Cancer Advisory Board was established, and appropriations in excess of $100 million were authorized for 1972, with further increases in subsequent years.

May 16, 1972—The National Sickle Cell Anemia Control Act of 1972 (P.L. 92-294) became law and establishes a national program for diagnosis and treatment of, and counseling and research in, sickle cell disease.

May 19, 1972—P.L. 92-305 emphasized the need for further support of research and training in the field of digestive diseases by adding a new Section 434 to the PHS Act and renaming NIAMD the National Institute of Arthritis, Metabolism, and Digestive Diseases.

August 29, 1972—The National Cooley's Anemia Control Act (P.L. 92-414) authorized over $9 million for three years for research in the diagnosis and treatment of Cooley's Anemia, and for counseling and public information programs.

September 19, 1972—P.L. 92-423, the National Heart, Blood Vessel, Lung, and Blood Act, expanded the authorities of the National Heart and Lung Institute to augment the national effort against heart, lung, and blood diseases. Appropriations of $375 million for 1973 were authorized with further increases in subsequent years.

October 25, 1972—P.L. 92-563, the National Commission on Multiple Sclerosis Act. The commission, comprised of nine members appointed by the HEW Secretary (five public members and four selected from the National Advisory Neurological Diseases and Stroke Council), is charged with determining the most productive avenue of researching possible causes and cures of multiple sclerosis, and making specific recommendations for the maximum utilization of national resources directed toward multiple sclerosis research.

June 18, 1973—P.L. 93-45, the Health Programs Extension Act of 1973, extended the medical library assistance programs of the National Library of Medicine (with the exception of the construction program) for one year. Population research and family planning activities were also extended through fiscal year 1974, along with other Federal health programs.

November 16, 1973—P.L. 93-154, the Emergency Medical Services System Act of 1973, amended the Public Health Service Act to provide assistance and encouragement for the development of comprehensive area emergency medical services systems, including grants and contracts for the support of research in emergency medical techniques, methods, devices, and delivery.

April 22, 1974—P.L. 93-270, Sudden Infant Death Syndrome Act of 1974, amended the Public Health Service Act to authorize specific and general research on the Sudden Infant Death Syndrome through the National Institute of Child Health and Human Development. The collection, analysis, and public dissemination of information and data and the support of counseling programs were also authorized. The act did not authorize specific funds for research, but did authorize appropriations of $9 million over a 3-year period for the other programs.

May 31, 1974—P.L. 93-296, the Research on Aging Act of 1974, established a National Institute on Aging. The act authorized the NIA to conduct and support biomedical, social, and behavioral research and training relating to the aging process and the diseases and other special problems and needs of the aged.

June 22, 1974—P.L. 93-319, the Energy Supply and Coordination Act, directs the Secretary through NIEHS to conduct a study of the effects of chronic exposure to sulfur oxides, and authorized $3.5 million for that purpose.

July 12, 1974—P.L. 93-348, the National Research Act of 1974, amended the Public Health Service Act by repealing existing research training and fellowship authorities and consolidating such authorities in the "National Research Service Awards" authority. The National Research Service Awards (both individual and institutional grants) are restricted on the basis of subject area shortages and would involve service obligations and payback provisions. The act also established a temporary National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research within DHEW to make a comprehensive investigation of the ethical principles involved in biomedical and behavioral research (including psychosurgery and living fetus research), and to develop ethical guidelines for conducting such research. Also, a permanent National Advisory Council for the Protection of Subjects of Biomedical and Behavioral Research is to be established.

July 23, 1974—P.L. 93-352, the National Cancer Act Amendments of 1974, authorized $2.565 billion over a 3-year period to extend and improve the National Cancer Program as well as $210.5 million over a 3-year period for cancer control programs. The act also: (1) established the President's Biomedical Research Panel to make a comprehensive investigation of Federal biomedical and behavioral research; (2) extended indefinitely the research contract authority of Section 301(h) of the PHS Act; (3) provided that the Director, NIH, shall be appointed by the President by and with the advice of the Senate, and (4) required peer review of NIH and ADAMHA grant applications and contract projects.

P.L. 93-353, the Health Services Research and Evaluation and Health Statistics Act of 1974, extended and amended the National Library of Medicine program authorities ($37.5 million over a 3-year period). The act also extended the Fogarty International Center's authority to engage in international cooperative efforts in health.

P.L. 93-354, the National Diabetes Mellitus Research and Education Act, provides for regional research and training centers ($40 million appropriations authorized over a 3-year period), a long-range plan prepared by a National Commission on Diabetes, expanded research and training programs, a Diabetes Mellitus Coordinating Committee, and an Associate Director for Diabetes in the National Institute of Arthritis, Metabolism, and Digestive Diseases.

APPENDIX B

Biomedical Research Areas Supported
by The National Institutes of Health

Appendix B

BIOMEDICAL RESEARCH AREAS

SUPPORTED BY THE NATIONAL INSTITUTES OF HEALTH

THE NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES supports a worldwide program of research on the causes, diagnosis, treatment, and prevention of allergic and infectious diseases. The Institute supports basic research on viruses, bacteria, parasites, and other microorganisms that cause disease in man, as well as research on the body's immunologic mechanisms and defenses against disease. The Institute especially encourages research on problems of national health importance including allergic and other immunologic disease, cellular and transplantation immunology, immunoprophylaxis, interferon and other antiviral substances, hepatitis, hospital and drug resistant infections, chronic and latent microbial infections, and biology of the gonococcus. The Institute also supports training for careers in research and academic medicine in the fields of allergy, immunology, acute and chronic infectious diseases, tropical medicine, and in the allied areas of cell biology, virology, mycology, bacteriology, parasitology, rickettsiology, epidemiology and genetics.

THE NATIONAL INSTITUTE OF ARTHRITIS AND METABOLIC DISEASES supports research into the causes, prevention, diagnosis, and treatment of the various arthritides, the rheumatic and callagen diseases, and the metabolic diseases, such as diabetes; other inborn errors of metabolism, such as cystic fibrosis; digestive diseases, orthopedics, dermatology, hematology, nutrition, endocrine disorders, energy and mineral metabolism, urology and kidney diseases and development of the artificial kidney machine. The program includes basic research in biochemistry, enzymology, nutrition, pathology, histochemistry, pharmacology, toxicology, and physical, chemical and molecular biology. The Institute also supports training programs, primarily to provide research experience and advanced clinical training, where relevant to the research experience, for individuals who wish to pursue academic careers in the areas of arthritis, dermatology, diabetes, endocrinology, digestive diseases, liver diseases, hematology, metabolism, nutrition, orthopedics, urology, and kidney diseases.

THE NATIONAL CANCER INSTITUTE supports programs for research on cancer cause and prevention, diagnosis, and treatment. These activities include virtually every investigative approach to the cancer problem, in such fields as biochemistry, biology, radiation physics, chemotherapy, epidemiology, endocrinology, immunology, physiology, and clinical medicine, surgery, and radiotherapy. Research progress has delineated three areas of currently intensive study: viruses as a possible cause of leukemia and other forms of human cancer, drug treatment of cancer, and cancer-causing chemicals in the environment. The NCI supports a number of Specialized Research Centers which are performing intensive, highly specialized clinical research or laboratory research, relating to cancer in man. These centers are organized on a single or multidiscipline basis to assist each other in developing new methods of diagnosis and treatment. A cooperative Clinical Program of the Institute encompasses approximately 20 groups of investigators conducting research on all therapeutic modalities, closely related preclinical projects and, to a lesser but increasing extent, epidemiology and diagnosis. In addition, the NCI supports fundamental and clinical research training in the medical disciplines that can be applied to problems in cancer; special emphasis has been placed on training radiation therapists and radiation biologists since these specialists have contributed to an increasing degree of improvement or cure among patients with cancer. The NCI also supports a clinical cancer training program to increase the quality of cancer instruction at one or more professional levels.

THE NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT provides funds for research grants to qualified scientists working in areas related to maternal health, child health, human growth and development, maturation and the aging process; also in reproductive biology, embryogenesis, perinatal biology, and causes of infant and fetal mortality. Through its Center for Population Research, special emphasis is placed on population research, including a program designed to support several population research centers in various parts of the country. The Institute also serves as a focal point for research on mental retardation, including support for twelve Mental Retardation Research Centers located throughout the country. The Institute also supports training programs primarily to provide research experience for individuals wishing to pursue academic careers in the areas of maternal and child health, growth and development, maturation and the aging process, reproductive and perinatal biology, mental retardation and population problems. Emphasis is placed on training in the social and behavioral sciences as well as in the biomedical sciences.

THE NATIONAL INSTITUTE OF DENTAL RESEARCH supports investigations into the causes, means of prevention, diagnosis and treatment of oral diseases including dental caries, periodontal diseases, lesions of soft and hard tissues, and oral-facial abnormalities such as cleft lip and palate. The goal of another important interest, biomaterials research, is to develop new and improved dental and cranio-facial resotrations and prostheses. Research to improve anesthesia and analgesia for the control of dental pain is another prime concern. Research supported ranges from basic and epidemiologic research to clinical trials and applications. The Institute also provides support in establishing or improving graduate training, primarily for research, but which may also include teaching experience. Training may be either in the nonclinical, health-related sciences or in an area which combines the clinical and basic sciences related to dentistry.

THE NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES supports fundamental research concerned with defining, quantifying, and understanding the effects of chemical, biological, and physical factors upon biological systems in relation to the health and well-being of man. The Institute's program interests encompass the epidemiology of environmental hazards and the development and utilization of experimental models that duplicate the circumstances of human exposure. Among factors considered are the mode of entry of noxious agents; the effects of concomitant or sequential exposure to multiple agents; the short- and long-term biological, morphological, and functional effects upon biological systems; and the condition of the host. The Institute also supports research training to increase the number and quality of research scientists involved in fundamental studies of the effects of environmental agents upon biological systems in relation to the health and well-being of man. Support may be provided to any area of a wide spectrum of the physical and biological sciences including biochemistry, biology, biometry, chemistry, clinical medicine, human ecology, engineering, epidemiology, pathology, pharmacology, physics, physiology, radiobiology, toxicology, and veterinary science. In addition to high-quality and intensive training in the discipline(s) involved, programs requesting support must emphasize both the acquisition of existing knowledge and active research concerned with the development of new knowledge about environmental health problems.

THE NATIONAL EYE INSTITUTE supports research on the causes, prevention, and treatment of disorders of the eye and the visual system. Its primary interests include fundamental studies of the eye and its adnexae, the optic nerve, optic tract, optic radiation, visual cortex, and associated portions of the central nervous system (sensory and motor), and the events occurring between the impingement of light on the retina and the conscious perception of an image; research on the natural history, etiology, pathogenesis and pathology, diagnosis, and treatment of visual disorders; and research on rehabilitation of the visually handicapped. The Institute also provides support for the establishment, expansion, and improvement of graduate training in the basic and clinical sciences relating to vision and its disorders. The purpose of the Institute's training programs is to provide research experience for individuals who wish to pursue careers in research and teaching the visual sciences.

THE NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES supports research in the sciences basic to medicine, in the behavioral sciences, and in certain clinical disciplines. Among the major objectives are to gain new knowledge for safer and more effective use of drugs; to improve diagnostic methods and services, especially by automating clinical laboratory processes; to solve problems in the therapy of trauma; to improve the administration of anesthesia and the clinical management of pain; and to achieve a greater understanding of genetic mechanisms, and of the structure and function of cells, including their substructures. Specific research fields of interest to the Institute are anesthesiology, the behavioral sciences in relation to disease, biochemistry, biomedical engineering, biophysics, cellular biology, clinical chemistry, diagnostic radiology, genetics and genetic chemistry, molecular biology, pharmacology and toxicology. The Institute also supports research training programs to increase the number and the skills of practicing anesthesiologists, and encourages training programs in new and rapidly developing biomedical disciplines.

THE NATIONAL HEART AND LUNG INSTITUTE supports basic and clinical research on the structure and function of the cardiovascular and respiratory systems and on the prevention, diagnosis, and treatment of heart and lung diseases. Major areas of research include: atherosclerosis; coronary heart disease; peripheral vascular disease; cerebrovascular disease; hypertension; renal physiology and diseases; thrombosis and hemorrhagic diseases; pulmonary structure, function, and diseases; heart failure and shock; congenital and rheumatic heart disease; cardio-vascular dynamics and circulatory regulation. The NHLI also supports Specialized Centers of Research to focus resources and research manpower on selected, high-priority problems in four disease areas: arteriosclerosis; pulmonary disease; thrombosis; and hypertension. The goal of these Centers is to develop new knowledge relevant to the prevention, diagnosis, and treatment of these diseases and to hasten the clinical application of this knowledge. The Institute also supports a variety of graduate training programs to assist and extend the training of individuals preparing for research and academic careers in fundamental, preclinical, clinical, public health, and other disciplines related to cardiovascular and pulmonary diseases. Through clinical training grants, the Institute supports specialized training in the most advanced clinical techniques for physicians in selected cardiovascular and pulmonary specialties. The NHLI has a new program of Pulmonary Academic Awards designed to improve pulmonary training programs in schools of medicine or osteopathy and to foster academic careers in the respiratory disease field.

NATIONAL INSTITUTE OF NEUROLOGICAL DISEASES AND STROKE research project and clinical research center programs stimulate and support investigations in the neurological, sensory, communicative, and related fields, including research concerned with the cause, development, diagnosis, therapy, and prevention of such disorders as: multiple sclerosis, cerebrovascular diseases, epilepsy, muscular dystrophy, head and spinal cord injury, cerebral palsy, mental retardation,encephalitides, Meniere's syndrome, aphasia, nerve deafness, otosclerosis, and other disorders of the nervous system, hearing equilibrium, and speech. In addition, support is provided for fundamental studies of the development, structure, and function of the nervous system, the neuromuscular appartus and human communication. The Institute also supports training programs, preparing personnel for academic careers in the neurological and communicative fields. Through training grants, fellowships and traineeships, funds are available in support of the training environment and of trainees at the graduate level.

THE DIVISION OF RESEARCH RESOURCES administers and manages broad programs intended to supply a wide institutional base of support for health-related research. The Division's principal concern is to help establish and operate a number of general clinical research centers where clinical research studies can be conducted over a wide range of human diseases; supply highly specialized research services and equipment; increase the availability of laboratory animals, including unusual species and special strains;—support regional primate research centers; and stimulate well-balanced institutional research programs through grants for general research support. The Division also provides funds on a continuing basis through general research support to health professional schools of medicine, dentistry, osteopathy, public health, pharmacy, and veterinary medicine, and to other nonprofit organizations engaged in health-related research for research training in the health sciences.

In addition, the Division supports postdoctoral training programs and fellowships in laboratory animal science and medicine.

THE NATIONAL LIBRARY OF MEDICINE supports projects for research, development, and demonstration in medical library science and biomedical communications. Projects include innovations in medical library services, advances in the information sciences, and utilization of information resources for health education. Support is also provided for training in biomedical communication research. To organize, interpret, and synthesize the accumulating store of health knowledge, selected biomedical writing and publication projects are supported. Such projects include shcolarly studies of the history of medicine and the sciences related to health.

DIVISION OF ALLIED HEALTH MANPOWER, BUREAU OF HEALTH MANPOWER EDUCATION supports investigation and demonstration projects to improve and to increase the training opportunities for allied health professions personnel. Emphasis is given to projects that focus on special issues, for example, equivalency and proficiency testing, training opportunities for minority groups, recruitment and counseling. Similar projects related to the training of health personnel for public health careers are supported. Particular emphasis is given to improve the training opportunities in preventive medicine and dentistry and health services administration.

THE DIVISION OF DENTAL HEALTH, BUREAU OF HEALTH MANPOWER EDUCATION supports research to increase the supply and improve the education and utilization of the Nation's dental manpower, to develop and improve the utilization of the dental services and resources of the country, to prevent and control dental diseases and disorders, to organize and operate dental care programs for specifically designated population groups, and to promote and extend provisions of dental services. The Division also supports training programs designed to increase the number and proficiency of individuals capable of conducting research in the fields of dental education, dental care delivery systems, oral hygiene education, and other applied areas relevant to dental manpower and the total dental care delivery system. Individual fellowships are supported to augment these programs and to complement them with trainees in special fields having a utility in dental health research, but in which the need for large numbers of individuals is not as great.

THE DIVISION OF NURSING, BUREAU OF HEALTH MANPOWER EDUCATION supports research to improve the nursing care of patients and increase the nursing contribution to health services. Its research projects reach into all areas of nursing education and practice and include study of problems of clinical practice, career choices, organization and delivery of nursing services, nursing as an occupation, identification of new scientific knowledge to improve the care and comfort of patients, and ways to further research application and thus encure the therapeutic consequence of nursing actions. The Division also supports research training programs, primarily to encourage nurses to train for research careers in nursing, to collaborate in inter-disciplinary research, and to stimulate and direct nursing research. Support is given to biomedical and behavioral research training which can be applied to problems of importance to nursing. Training is supported in nursing disciplines and in anatomy, anthropology, biology, epidemology, microbiology, physiology, psychology, and sociology; and in such health-related fields as biometry, biomedical communications, health organization, health economics and human development.

THE DIVISION OF PHYSICIAN AND HEALTH PROFESSIONS EDUCATION, BUREAU OF HEALTH MANPOWER EDUCATION administers grant, loan, and operational programs to enable institutions to improve the quality of their education and to increase the supply of manpower in the fields of medicine, osteopathy, dentistry, optometry, pharmacy, and veterinary medicine. Financial support for educational programs of the health profession schools is provided by institutional and special project grants under the Health Professions Educational Improvement Program. Construction grants, awarded to health professions schools by the Division, assist them to expand, maintain, or renovate their physical facilities to increase or maintain enrollemnt capacity. The Division also administers a loan and scholarship program for students in health professions.

NOTE: Legislation pending on BHME programs

APPENDIX C

Awarding Units, Review Bodies and Program Types Supported by the National Institutes of Health

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ACTIVITY CODES, ORGANIZATIONAL CODES and DEFINITIONS used in EXTRAMURAL PROGRAMS

IMPAC N I H

A Computer-Based Information System
on the Extramural Programs of N I H

Statistics and Analysis Branch
Division of Research Grants
National Institutes of Health
September 1975
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ACTIVITY CODES, ORGANIZATIONAL CODES, AND DEFINITIONS USED IN EXTRAMURAL PROGRAMS *

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* This pamphlet supersedes that dated September 1974. Address all questions concerning the contents and requests for additional copies to Chief, Statistics and Analysis Branch, DRG.

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ACTIVITY CODES, ORGANIZATIONAL CODES, AND DEFINITIONS USED IN EXTRAMURAL PROGRAMS

INTRODUCTION

The purpose of this pamphlet is to present the various activity and organizational codes and definitions used in the NIH IMPAC System to identify NIH extramural activities. It also provides a detailed description of the NIH application/grant and contract identification numbering systems currently used by the NIH IMPAC System. IMPAC is an acronym for Information for Management, Planning, Analysis, and Coordination, and represents a sophisticated, computer-based information system dealing with the extramural programs of NIH.

Below and on the following pages are a description of the application/grant and contract identification systems, lists of codes appearing on applications, award statements, correspondence, etc., and related code translations and definitions. The pamphlet generally reflects those codes currently recorded on the Pending and Open Files of the IMPAC System, with the exception of those codes representing the awarding organizations. The organizational codes reflect the status of the DHEW health-related organizations as of July 1, 1975.

GRANT APPLICATION/AWARD IDENTIFICATION NUMBERING SYSTEM

The grant identification number, consisting of several parts each having a distinct meaning, is structured as follows:

Application Type	Activity Code	Awarding Organization	Serial Number	Suffixes	
				Grant Year	Other
3	R01	CA	00900	-04	A1S1

Application Type - A single-digit code identifying the type of application received and processed (New, Renewal, Supplement, etc.). Codes and related definitions are included in the text (see pp.4 and 15).

Activity Code - A three-digit code identifying a special grant or contract activity generally applicable to two or more awarding units. Codes and related definitions are included in the text (see pp. 6 and 18).

Awarding Organization - A two-letter code identifying the first major level subdivision of the National Institutes of Health. (Organizations having Bureau status may be identified at the Division level.) Codes are included in the text (see p. 4).

INTRODUCTION (Continued)

Serial Number - A five-digit number generally assigned sequentially within an Institute or Division series.

Suffixes

Grant Year - A two-digit number indicating the actual segment or budget period of a project. The grant year number (01, 02, 03, etc.) is preceded by a dash to separate it from the serial number; e.g., AM 12345-01, CA 00900-04, PE 56789-06. This series of years continues through succeeding renewals.

Supplement - The letter "S" and related number identifying a particular supplemental award, for example, S1, S2, S3, etc. Supplement designations follow the grant year or the amendment designation, as the case may be; e.g., AM 12345-01S1 and CA 00900-04A1S1.

Amendment - The letter "A" and related number identifying each amended application; for example, A1, A2, A3, etc. Amendment designations follow the grant year or the supplement designation, as the case may be; e.g., DE 34567-02A1 and DE 45678-01S1A1.

The identification number is commonly referred to as the application number or grant number, depending upon the processing status after the application has been received. The example, 3 R01 CA 00900-04A1S1, is the assignment given to a supplemental (Type 3) application in support of a traditional research project (R01) referred to the National Cancer Institute (CA). The number further identifies the application serially as the 900th submitted to the NCI, and indicates that the support is for the first supplement to the amended fourth (-04A1S1) year.

CONTRACT IDENTIFICATION NUMBERING SYSTEM

The contract identification number, consisting of several parts each having a distinct meaning, is structured as follows:

Type of Transaction	Activity Code	Awarding Organization	Serial Number	Transaction Number
1	N01	AI	32502	00

Type of Transaction - A single-digit code identifying the type of contract transaction (New, Renewal, Modification, etc.). Codes and related definitions are included in the text (see pp. 4 and 16).

Activity Code - A three-digit code "N01" denoting NIH research project contracts.

Awarding Organization - A two-letter code identifying the first major level subdivision of the National Institutes of Health. (Organizations having Bureau status may be identified at the Division level.) Codes are included in the text (see p. 4).

INTRODUCTION (Continued)

Serial Number - A five-digit number assigned by the BID Contracting Office to number sequentially all contracts or basic agreements executed. The first digit indicates the fiscal year (e.g., 32502 indicates fiscal year 1973); the last four digits, the serial number. Generally basic agreement numbers are assigned by OCG which negotiates and administers most NIH basic agreements.

Transaction Number - After the serial number is a dash followed by the transaction number. This is a two-digit number indicating the number of the transaction pertaining to the specific contract or basic agreement. Transaction numbers are assigned sequentially from 00-99. The number 00 indicates a new contract or basic agreement; 01 the first modification to the specific contract or basic agreement; etc.

"Application Type," "Activity," and "Institute or Division" codes are important parts of the identifying number which appears on applications, award statements, contracts, etc. To avoid confusion and to expedite the processing of correspondence, and in instances of external record systems, the entire number should be used; e.g., 3 R01 AM 06722-03S1, 1 F05 TW 01435-01 and 1 N01 CB 32502-01.

INITIAL REVIEW GROUP CODES

All Initial Review Groups are designated by special acronyms or alphabetical codes, with a maximum of four (4) characters per code. These designations are normally posted to incoming applications upon receipt; for example, HEM, GEN, etc. They also appear frequently in reports and on award statements. Codes and related translations are included in the text (see p. 10).

PROCEDURES GOVERNING CODE AUTHORIZATIONS

1. New activities must have preliminary approval from the office of the NIH Associate Director for Extramural Research & Training (ADERT) prior to SAB authorization of new codes.

2. Requests for new codes, changes, or corrections are addressed to Statistics and Analysis Branch, DRG, with supporting information attached; e.g., memorandums, policy statement(s), enabling legislation, etc.

3. The Statistics and Analysis Branch, DRG, reviews, coordinates, and authorizes the use of all applicable codes.

4. New codes are announced as authorization is granted.

SECTION 1 - CODES (GRANTS AND CONTRACTS)

APPLICATION TYPES

Code	
	GRANTS
1	New
2	Competing Renewal
3	Supplement
4	Noncompeting Renewal (extension; fellowship programs)
5	Continuation
6	Change of Institute or Division (new; training programs)
7	Change of Grantee or Training Institution
8	Change of Institute or Division (continuation)
9	Change of Institute or Division (competing renewal)
	CONTRACTS
1	New Contract
2	Renewal
3	Modification
4	Letter Contract
5	Continuation of Incrementally Funded Contract
7	Basic Agreement
9	Change of Contract Number

AWARDING ORGANIZATIONS [1]

	National Institutes of Health (NIH)
AG	National Institute on Aging (NIA)
AI	National Institute of Allergy and Infectious Diseases (NIAID)
AM	National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD)
	National Cancer Institute (NCI)
CA	Division of Cancer Research Resources and Centers (NCI)
CO [2]	Office of the Director (NCI)
CN [2]	Division of Cancer Control (NCI)
CB [2]	Division of Cancer Biology and Diagnosis (NCI)
CP [2]	Division of Cancer Cause and Prevention (NCI)
CM [2]	Division of Cancer Treatment (NCI)
CL	Clinical Center (CLC)
CT	Division of Computer Research and Technology (DCRT)
DE	National Institute of Dental Research (NIDR)
ES	National Institute of Environmental Health Sciences (NIEHS)
EY	National Eye Institute (NEI)
GM	National Institute of General Medical Sciences (NIGMS)
HD	National Institute of Child Health & Human Development (NICHD)

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[1] Relates only to those organizations which actively participate in the IMPAC system as of July 1, 1975.

[2] Applicable to contracts only.

SECTION 1 - CODES (GRANTS AND CONTRACTS)

AWARDING ORGANIZATION (Continued) 1/

Code	
HL	National Heart and Lung Institute (NHLI)
HV	2/ Division of Heart and Vascular Diseases (NHLI)
HB	2/ Division of Blood Diseases and Resources (NHLI)
HR	2/ Division of Lung Diseases (NHLI)
HI	2/ Division of Intramural Research (NHLI)
HO	2/ Office of the NHLI Director (NHLI)
NS	National Institute of Neurological and Communicative Disorders & Stroke (NINCDS)
OD	Office of the NIH Director (OD)
RG	Division of Research Grants (DRG)
RR	Division of Research Resources (DRR)
RS	Division of Research Services (DRS)
TW	Fogarty International Center (FIC)
LM	National Library of Medicine (NLM)
JT	Joint Contract Sponsorship (JOINT)
	Health Resources Administration (HRA)
MB	Office of the Bureau of Health Manpower Director (BHM)
AH	Division of Associated Health Professions (DAHP-BHM)
DH	Division of Dentistry (DD-BHM)
HS	National Center for Health Services Research (NCHSR)
MI	Manpower Intelligence (HRA)
NU	Division of Nursing (DNU-BHM)
PE	Division of Medicine (DM-BHM)
	Food and Drug Administration (FDA)
FD	Food and Drug Administration (FDA)
RL	Bureau of Radiological Health (BRH)
	Center for Disease Control (CDC)
CC	Center for Disease Control (CDC)
OH	National Institute of Occupational Safety and Health (NIOSH)
	Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA)
AA	National Institute on Alcohol Abuse and Alcohol (NIAAA)
DA	National Institute on Drug Abuse (NIDA)
MH	National Institute of Mental Health (NIMH)

1/ Relates only to those organizations which actively participate in the IMPAC system as of July 1, 1975.

2/ Applicable to contracts only.

ACTIVITIES [1]

RESEARCH

Research Projects

Code	
R 01	Projects (traditional)
R 02	Nursing
R 03	Small Grants
R 07	ICMR - International Centers for Medical Research (NIAID)
R 09	Scientific Evaluation
R 10	Cooperative Clinical Research, Chemotherapy, and Psychopharmacology
R 12	Mental Health Special Grants
R 13	Conferences (traditional)
R 18	Research Demonstration and Dissemination Projects
R 21	Exploratory Grants
R 22	U.S. - Japan Cooperative Medical Science Program
R 23	Special Research Award Program
R 24	Resource-Related Research Projects - Biotechnology Resources (DRR)
R 25	Education Projects
R 26	National Organ Site Projects (NCI)
R 27	Grants for Computer Technology Health Care Demonstration (BHM-HRA)
R 28	Resource-Related Research Projects - General Clinical Research Centers (DRR)

Program Projects and Centers [2]

M 01	General Clinical Research Centers (DRR)
P 01	Research Program Projects
P 02	Categorical Clinical Research Centers
P 06	Animal Resources (DRR)
P 07	Biotechnology Resources (DRR)
P 09	Scientific Evaluation
P 10	Environmental Health Centers (NIEHS)
P 11	Pharmacology - Toxicology Centers (NIGMS)
P 13	Dental Research Institute Program (NIDR)
P 15	Outpatient Clinical Research Program
P 16	Research and Demonstration Centers
P 17	Specialized Centers of Research
P 18	Sickle Cell Centers (NHLI)
P 20	Exploratory Grants
P 30	Core Center Grants
P 40	Animal Resource Grant Program
P 41	Biotechnology Resource Grant Program
P 50	Specialized Center
P 60	Comprehensive Center

General Support (Research Related)

S 01	General Research Support (DRR)
S 04	Health Sciences Advancement Award (DRR)
S 05	Biomedical Sciences Support Grant (DRR)
S 06	Minority Biomedical Support - MBS (DRR)

[1] Represents all activity codes on the Pending and Open files of the IMPAC System in use as of July 1, 1975.

[2] Beginning July 1, 1975, all "P" series active grants and applications were reassigned to appropriate P01, P09, or P20-60 codes.

ACTIVITIES (Continued) 1/

CONSTRUCTION

Code	
C 05	Educational & Research Facilities Construction (DM, DNU, DAHP-HRA)
C 06	Cancer Research Facilities (NCI)

TRAINING

Applied Training

A 02	Allied Health Professions Traineeship Grants for Advanced Training (DAHP-HRA)
A 03	General Purpose Traineeship Grants to Schools of Public Health (DAHP-HRA)
A 04	Special Purpose Traineeship Grants (DAHP-HRA)
A 05	Public Health Nursing Traineeship Grants to Colleges and Universities (DAHP-HRA)
A 06	Traineeship Grants for Short-Term Training (DAHP-HRA)
A 07	Traineeship Grants for Apprenticeship Training (DAHP-HRA)
A 08	Residency Traineeship Grants in Preventive Medicine and Dentistry (DAHP-HRA)
A 10	Environmental Health Traineeship Grants (DAHP-HRA)
A 11	Professional Nurse Traineeship (long-term) (DNU-HRA)
A 12	Professional Nurse Traineeship (short-term) (DNU-HRA)
A 13	Allied Health Professions Grants for Training Institutes (DAHP-HRA)
A 14	Occupational Safety and Health Professions Grants for Training Institutes - Short Term (NIOSH-CDC)
A 15	Grants for Training and Traineeships for Health Professions Teaching Personnel (DM-HRA)

Training Program Projects

D 01	Allied Health Professions Special Improvement Grants (DAHP-HRA)
D 02	Developmental Grants
D 04	Project Grants for Graduate Training in Public Health (DAHP-HRA)
D 06	Dental Auxiliary Utilization Program (DD-HRA)
D 07	Continuing Education Training Program (DD-HRA)
D 08	Health Professions Special Project Grants (DM-HRA)
D 10	Nursing Special Project Grants (DNU-HRA)
D 11	Dental TEAM Program Grants (DD-HRA)
D 12	Allied Health Professions Special Project Grants
D 14	Grants to Assist Health Professions Schools in Financial Stress (DM-HRA)
D 15	Grants for Training in Family Medicine (DM-HRA)
D 16	Grants for Start-Up Assistance (HRA)
D 17	Nursing Financial Distress Grants (DNU-HRA)
D 18	Special Health Career Opportunity Grants (BHM-HRA)
D 19	Grants for Utilization of Nursing Educational Talent (DNU-HRA)
D 20	Health Sciences and Computer Technology (NLM/BHM)
D 21	Health Manpower Education Initiative Projects (BHM-HRA)
D 22	Grants to Assist District of Columbia Medical & Dental Schools (BHM-HRA)

1/ Represents all activity codes on the Pending and Open Files of the IMPAC System in use as of July 1, 1975.

ACTIVITIES (Continued) 1/

General Support (Educational)

Code	
E 02	Formula Grants to Schools of Public Health (DAHP-HRA)
E 03	Health Professions Capitation Grants (DM-HRA)
E 04	Nursing Capitation Grants (DNU-HRA)
E 06	Grants for Conversion of Two-Year Schools of Medicine (DM-HRA)
E 07	Categorical Education Grants (ADAMHA)

Fellowships

F 01	Predoctoral
F 02	Postdoctoral
F 03	Special (Individual)
F 04	Nursing (DNU-HRA)
F 05	International (FIC)
F 06	Senior International Fellowship Program (FIC)
F 09	Scientific Evaluation
F 10	Fellowship Traineeship (NINCDS)
F 12	Medical Scientist Fellowship (NIGMS)
F 14	MARC Faculty Fellowships (NIGMS)
F 15	Fogarty International Scholarships (FIC)
F 16	MARC Visiting Scientist Fellowships (NIGMS)
F 17	Clinical Fellowship Program
F 22	Individual Research Fellowships
F 31	Predoctoral Individual National Research Service Award (ADAMHA)
F 32	Postdoctoral Individual National Research Service Award

Research Career Program Awards

K 01	Research Scientist Development Award - Research & Training
K 02	Research Scientist Development Award - Research
K 03	Research Career Development Award
K 04	Modified Research Career Development Award
K 05	Research Scientist Award (ADAMHA)
K 06	Research Career Award
K 07	Academic Career Award
K 08	Clinical Investigator and Faculty Development Award
K 09	Scientific Evaluation
K 10	Special Scientific Projects (NLM)

1/ Represents all activity codes on the Pending and Open Files of the IMPAC System in use as of July 1, 1975.

ACTIVITIES (Continued) 1/

Research Training

Code	
T 01	Graduate
T 02	Undergraduate
T 05	Medical Scientist Training Program (NIGMS)
T 07	Program for Experimental Training for Clinical Investigation (NIAMDD)
T 09	Scientific Evaluation
T 10	Hospital Staff Development Program (NIMH)
T 14	Conferences
T 15	Continuing Education Training Program
T 17	Development Training
T 21	Pilot Projects (ADAMHA)
T 22	Institutional Research Fellowships
T 31	Special Projects (ADAMHA)
T 32	Institutional National Research Service Award
T 41	Utilization and Development (ADAMHA)

FOREIGN CURRENCY

W 01	Special Foreign Currency (PL 480) Program

AGREEMENTS

Y 01	Interagency and Intraagency Agreements

OTHER GENERAL SUPPORT

G 01	Medical Library Resource (NLM)
G 04	Regional Medical Library Program (NLM)
G 07	Resources Improvement Grant (NLM)
G 08	Resources Project Grant (NLM)

CONTRACTS

N 01	Research and Project Contracts

HEALTH SERVICES

H 84	Prevention, Treatment and Rehabilitation Grants (ADAMHA)

1/ Represents all activity codes on the Pending and Open Files of the IMPAC System in use as of July 1, 1975.

INITIAL REVIEW GROUPS

Code	Study Sections (DRG when not specified)
APB	Applied Physiology and Bioengineering
ALY	Allergy and Immunology
BBCA	Biophysics and Biophysical Chemistry A
BBCB	Biophysics and Biophysical Chemistry B
BCM	Biomedical Communications
BIO	Biochemistry
BM	Bacteriology and Mycology
CBY	Cell Biology
CDC	Communicable Disease Control (CDC)
CMS	Communicative Sciences
COM	Computer and Biomathematical Sciences
CTY	Molecular Cytology
CVA	Cardiovascular and Pulmonary
CVB	Cardiovascular and Renal
DBR	Developmental Behavioral Sciences
DEN	Oral Biology and Medicine (discontinued - see OBM)
EDC	Epidemiology and Disease Control
END	Endocrinology
ET	Experimental Therapeutics
EUH	Engineering and Urban Health Sciences (HRA)
EVR	Experimental Virology
EXP	Experimental Psychology
GEN	Genetics
GMA	General Medicine A
GMB	General Medicine B
HCT	Health Care Technology (NCHSR-HRA)
HED	Human Embryology and Development
HEM	Hematology
HSDG	Health Services Developmental Grants (NCHSR-HRA)
HSR	Health Services Research (NCHSR-HRA)
IMB	Immunobiology
IMS	Immunobiological Sciences
MBC	Microbial Chemistry
MBY	Molecular Biology
MCHA	Medicinal Chemistry A
MCHB	Medicinal Chemistry B
MET	Metabolism
NEUA	Neurology A
NEUB	Neurology B
NTN	Nutrition
OBM	Oral Biology and Medicine
PBC	Pathobiological Chemistry
PC	Physiological Chemistry
PHRA	Pharmacology
PHY	Physiology

INITIAL REVIEW GROUPS

Code

Study Sections (Continued)

POP	Population Research
PTHA	Pathology A
PTHB	Pathology B
RAD	Radiation
REB	Reproductive Biology
SGYA	Surgery A
SGYB	Surgery B
SOH	Safety and Occupational Health (CDC)
SSS	Special Study Section
TMP	Tropical Medicine and Parasitology
TOX	Toxicology
VISA	Visual Sciences A
VISB	Visual Sciences B
VR	Virology

Program Project Committees

AMLS	Automation in the Medical Laboratory Sciences Review Committee (NIGMS)
AMP	Arthritis & Metabolic Diseases (NIAMDD)
CAP	Cancer (NCI)
DEP	Dental (NIDR)
GMP	General Medical Research (NIGMS)
HEP	Heart (NHLI)
MHP	Clinical Program Projects Research Review (NIMH)
NSPA	Neurological Disorders Program Project Review A Committee (NINCDS)
NSPB	Neurological Disorders Program Project Review B Committee (NINCDS)

Resources and Centers Committees

AR	Animal Resources (DRR)
CLR	Clinical Research Centers (DRR)
ICC	International Centers Committee (NIAID)
PME	Advisory Committee on Primate Research Centers (DRR)
PTR	Pharmacology - Toxicology Review Committee (NIGMS)

Training Committees

ALT	Alcohol Training Review Committee (NIAAA)
BLS	Biological Sciences (NIMH) (Abolished)
BPHS	Biophysical Sciences (NIGMS)
CET	Continuing Education Training Review Committee (NIMH)
CLCH	Clinical Chemistry (Ad hoc-NIGMS)
CT	Cancer Institutional Fellowship Review Committee (NCI)

INITIAL REVIEW GROUPS

Training Committees (Continued)

Code	
DAST	Special Review-Training (NIDA)
DENT	Dental Education Review Committee (DM-HRA)
EXT	Experimental and Special Training Review Committee (NIMH)
GIN	Gastroenterology - Nutrition (NIAMDD)
GMK	Research Career Awards (NIGMS)
HST	Health Services Research Training Committee (NCHSR-HRA)
MBS	Multidisciplinary Biology (Ad hoc-NIGMS)
MCL	Mammalian Cell Line Committee (NIGMS)
MDC	Pharmacology and Toxicology - Medicinal Chemistry (NIGMS)
MHK	Research Scientist Development Review Committee (NIMH) (Abolished)
MO	Medicine & Osteopathy Special Project Grants Review Committee (DM-HRA)
NC	Mental Health New Careers Training Committee (NIMH) (Abolished)
NCR	No Committee Review (all Institutes)
NTS	Nutritional Sciences (NIGMS)
NTST	Professional Nurse Traineeship Program - Short-Term Review Committee (DNU-HRA)
NUR	Nursing (NIMH) (Abolished)
OPMY	Optometry Review Committee (DM-HRA)
PAY	Pathology (NIGMS) (Abolished)
PG	Nurse Training Act Project Grants Review Committee (DNU-HRA)
PHAR	Pharmacy Review Committee (DM-HRA)
PHRM	Pharmacology and Toxicology - Pharmacology (NIGMS)
PI	Psychiatry (NIMH) (Abolished)
PO	Psychology (NIMH) (Abolished)
POD	Podiatry Review Committee (DM-HRA)
SS	Social Sciences (NIMH) (Abolished)
STC	Special Review
SUR	Surgery Training Committee (NIGMS)
SW	Social Work (NIMH) (Abolished)
TXY	Pharmacology and Toxicology Research Program Committee (NIGMS)
VET	Veterinary Medicine Review Committee (DM-HRA)

Fellowship Committees

CUAN	Cultural Anthropology (NIMH)
IFRC	International (FIC)
IRRP	International Research Review Panel (FIC)
MHSF	Special Review - Fellowships (NIMH)
MRC	Minority Access to Research Careers Review Committee (NIGMS)
MTLH	Clinical and Personality Sciences (NIMH)
PS	Psychological Sciences (NIMH)
SRAP	Scholars-in-Residence Advisory Panel (FIC)

INITIAL REVIEW GROUPS

Code	Other Groups
AIRC	Allergy and Immunology Research Committee (NIAID)
ALC	Alcohol Research Review Committee (NIAAA)
AHR	Ad Hoc Review (Special purpose code - not for use as a committee assignment)
ASRB	Special Review - Public Inebriate; Drinking Driver; Poverty Alcoholism; Demonstrations, Surveys (NIAAA)
ASRC	Special Review - Community Assistance (NIAAA)
ASRI	Special Review - Indian Alcoholism (NIAAA)
ASRO	Special Review - Occupational Alcoholism (NIAAA)
ASRP	Special Review - Community Prevention; Youth Education (NIAAA)
BLR	Biomedical Library Review Committee (NLM)
BP	Bladder-PROSTATE Cancer Advisory Committee (NCI)
CAK	Cancer Special Program Advisory Committee (NCI)
CCG	Cancer Control Grants Review Committee (NCI)
CCI	Cancer Clinical Investigation Review Committee (NCI)
CD	Crime and Delinquency Review Committee (NIMH)
CDE	Dental Health Research and Education Advisory Committee (DD-HRA)
CDR	Communicative Disorders Review Committee (NINCDS)
CEC	Clinical Cancer Education Committee (NCI)
CPP	Clinical Psychopharmacology Research Review Committee (NIMH)
CPR	Clinical Projects Research Review Committee (NIMH)
CRC	Construction Review Committees (BHM-HRA)
DASR	Special Review Research (NIDA)
DSR	Dental Research Institute Review Committee (NIDR)
EPR	Experimental Psychology Research Review Committee (NIMH)
ESR	Epidemiologic Studies Review Committee (NIMH)
GRS	General Research Support Program Advisory Committee (NICHD)
HDAG	Adult Development and Aging Research & Training Committee (NICHD)
HDMC	Maternal and Child Health Research Committee (NICHD)
HDMR	Mental Retardation Research and Training Committee (NICHD)
HDPR	Population Research and Training Committee (NICHD)
HBP	National High Blood Pressure Education Research Program Committee (NHLI)
JP	Juvenile Problems Research Review Committee (NIMH)
LB	Colon-Rectum (Large Bowel) Cancer Advisory Committee (NCI)
LTC	Long-Term Care for the Elderly-Research Review and Advisory Committee (NCHSR-HRA)
MHS	Mental Health Services Research Review Committee (NIMH)
MN	Minority Group Mental Health Program Review Committee (NIMH)
MP	Metropolitan Mental Health Problems Review Committee (NIMH)
MPO	Health Manpower Opportunity Advisory Committee (BHM-HRA)
MSM	Mental Health Small Grant Committee (NIMH)
NAD	Drug Abuse Research Review Committee (NIDA)
NP	Neuropsychology Research Review Committee (NIMH)

INITIAL REVIEW GROUPS

Other Groups (Continued)

Code	
NRE	Nursing Research and Education Advisory Committee (DNU-HRA)
NSS	No Initial Review Group
PCR	Personality and Cognition Research Review Committee (NIMH)
PPR	Preclinical Psychopharmacology Research Review Committee (NIMH)
RRT	Radiological Health Research & Training Grants Review Committee (FDA)
SP	Special Problems Research Review Committee (NIMH)
SRC	Special Review
SSR	Social Sciences Research Review Committee(NIMH)
SUP	Suicide Prevention Review Committee (NIMH)
TEC	Clinical Trials Review Committee (NHLI)
VSN	Vision Research Program Committee (NEI)
YIP	Pulmonary Young Investigator Grant Committee (NHLI)

SECTION II - CODE DEFINITIONS (GRANTS AND CONTRACTS)

GRANT APPLICATION TYPES

Code	Definition
1	New - Identifies an original request for Public Health Service support of a particular project or activity.
2	Competing Renewal - Identifies a request for additional support beyond that previously recommended and must compete for available funds.
3	Supplement - Identifies a request for additional funds either for the current operating year or for any future year previously recommended.
4	Noncompeting Renewal - Identifies a request for additional support beyond that previously recommended and does not compete for available funds (Fellowships and Research Career Programs only).
5	Continuation - Identifies a request to award previously recommended support and does not compete for available funds.
6	Change of Institute or Division (new) - Identifies an original request for support (Type 1) of a project or activity that has been transferred from one awarding organization to another (Fellowships and Training Programs only).
7	Change of Grantee or Training Institution - Identifies a request for support of a project or activity that has been transferred from one grantee or training institution to another.
8	Change of Institute or Division - Identifies a request to award previously recommended support (Type 5) of a project or activity that has been transferred from one awarding organization to another.
9	Change of Institute or Division - Identifies a request competing for renewal support (Type 2) of a project or activity that has been transferred from one awarding organization to another.

CONTRACT TRANSACTION TYPES

Code	Definition
1	New Contract - Document covering a new work requirement which defines the specifications, conditions, and negotiated clauses pertaining to a contractual agreement between the government and a contractor. If a basic agreement exists with the contractor, the contractual document sets forth the scope of work, price, delivery, and additional matters peculiar to the particular procurement and incorporates by reference or appends the negotiated clauses agreed upon in the basic agreement.
2	Renewal - Supplemental agreement to an existing contract with the incumbent contractor which provides for the performance of new or additional work similar or identical in nature to that previously required, obligates additional funds, and extends the performance period for more than six months (usually for one year). (A renewal will not be executed on a competitive award, instead a new contract will be executed.)
3	Modification - Document altering or amending one or more provisions of an existing contract or basic agreement. (If funds are provided for additional work which necessitates extending the performance period in excess of six months, a supplemental agreement (renewal) should be executed.)
4	Letter Contract - Written preliminary contractual document which authorizes immediate commencement of work and stipulates maximum fund obligations which may be incurred prior to negotiation of a definitive contract. A letter contract will be superseded by definitive contract at the earliest practicable date, usually within 90 days.
5	Continuation of Incrementally Funded Contract - Supplemental agreement which allots funds for the next increment of work to be performed under a multiple year, incrementally funded contract, and stipulates additional time period covered by such allotment.

Code	Definition
7	Basic Agreement - Written agreement between the government and a contractor which sets forth the negotiated contract clauses applicable to all contracts with that contractor.
9	Change of Contract Number - Code 9 will be used only when an existing contract with an incumbent contractor has been renewed for a period of six months or more and action has been initiated to close out the former contract.

ACTIVITIES

RESEARCH

Code

Research Projects

R 01 Project Grants

To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

R 02 Research Project Grants - Nursing

To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in the area of nursing.

R 03 Small Grants

To support for one year or less, in amounts generally limited to a maximum of $5,000 for direct costs, in a relatively rapid and flexible manner, studies in behavioral, biological and medical sciences relevant to mental health; for support of preliminary research explorations. (In extraordinary circumstances, awards up to $6,000 will be made.)

R 07 ICMR (International Centers for Medical Research)

To provide for international cooperation in health research and planning by developing collaborative biomedical research programs between U. S. universities and selected foreign institutions and investigators. An ICMR is a discrete organization, sponsored by a professional school (medical and/or public health), which provides a stable, continuing base on which to conduct programs of health related research and planning, both in the U. S. and abroad, primarily through the development of a research center overseas.

R 09 Scientific Evaluation

To provide the chairman of an initial review group funds for operation of the review group.

Research Projects (Continued)

Code

R 10 **Cooperative Clinical Research, Chemotherapy and Psychopharmacology Research Grants**

To support clinical evaluation of various methods of therapy in specific disease areas. These are usually collaborative programs between sponsoring institutions and principal investigators, and usually conducted under a formal protocol.

R 12 **Mental Health Special Grants**

To provide support for: (1) collaborative clinical evaluation and testing of drugs where formal protocols are developed and where continual technical assistance is provided by NIMH; and (2) individual applications for research grant support which reflect staff initiative and which require continual technical assistance.

R 13 **Conference**

To support international or national meetings, conferences, and workshops.

R 18 **Research Demonstration and Dissemination Projects**

To provide support designed to develop, test, and evaluate health service activities, and to foster the application of existing knowledge for the control of categorical diseases.

R 21 **Exploratory Grants**

To encourage the development of new research programs in the area of community health. These awards are made for a maximum period of 2 years at a level not to exceed $20,000 per year (direct costs)

R 22 **U.S.-Japan Cooperative Medical Science Program**

To support research, for the benefit of the people of Asia, confined to six specifically limited medical problem areas: cholera, leprosy, malnutrition, the parasitic diseases schistosomiasis and filariasis, tuberculosis, and certain viral diseases (primarily rabies and dengue hemorrhagic fever) Program emphasis is upon medical research as the basis for advanced knowledge necessary to effective action.

R 23 **Special Research Award Program**

To support basic and clinical studies so that newly trained investigators remain active during the developmental stage of their career.

Research Projects (Continued)

Code

R 24 Resource-Related Research Projects - Biotechnology Resources

To support research projects contributing to improvement of the capability of resources to serve biomedical research.

R 25 Education Projects

For support to develop and/or carry out a program as it relates to a categorical area in one or more of the areas of education, information, training, technical assistance, coordination or evaluation.

R 26 National Organ Site Projects

To establish a planned coordinated cancer program with day-to-day management decisions being made at an institution other than the National Cancer Institute; to demonstrate the feasibility of decentralizing some aspects of NIH research programs and take advantage of existing institutional resources for managing large-scale biomedical programs.

R 27 Grants for Computer Technology Health Care Demonstration

To plan and develop free-standing or university-based computer laboratories which would establish computer-based systems, including compatible languages, standard terminologies, communication networks, and decision-making strategies, to enable the utilization of modern computer technologies by physicians and other health personnel in the provision of health services and in the processing of biomedical information relating to the provision of such services.

R 28 Resource-Related Research Projects - General Clinical Research Centers

To support research projects contributing to improvement of the capability of resources to serve clinical research.

Program Projects & Centers

M 01 General Clinical Research Centers Program

An award made to an institution solely for the support of a General Clinical Research Center where scientists conduct studies on a wide range of human diseases using the full spectrum of the biomedical sciences. Costs underwritten by these grants include those for renovation, for operational expenses such as staff salaries, equipment, and supplies, and for hospitalization. A General Clinical Research Center is a discrete unit of research beds separated from the general care wards.

Program Projects & Centers (Continued)

Code

P 01 Research Program Projects

For the support of a broadly based, multidisciplinary, often long term research program which has a specific major objective or a basic theme. A program project generally involves the organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective. Each research project is usually under the leadership of an established investigator. The grant can provide support for certain basic resources used by these groups in the program, including clinical components, the sharing of which facilitates the total research effort. A program project is directed toward a range of problems having a central research focus in contrast to the usually narrower thrust of the traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort; these scientifically meritorious projects should demonstrate an essential element of unity and interdependence, i.e., a system of research activities and projects directed toward a well-defined research program goal.

P 02 Categorical Clinical Research Centers

For support of basic physical resources and integrated system of resources and services essential to the conduct of a broad program of research. Generally for resources usable for a wide spectrum of studies, but may be oriented to a single group of diseases, disorders, or disciplines, if such are required.

P 06 Animal Resources

To plan, implement, and establish a national effort to provide animals of the kind and quantity needed for all branches of specialized medical research.

P 07 Biotechnology Resources

An award made to an institution in the name of one or more investigators to make available highly specialized equipment and associated technical skills to all qualified biomedical investigators without regard to their formal scientific disciplines or disease orientation of their research activities.

Program Projects & Centers (Continued)

Code

P 09 Scientific Evaluation

To provide the chairman of a program project committee funds for operation of the review committee.

P 10 Environmental Health Centers

An award made to an institution in the name of one or more investigators to provide long-term stable support for broadly based research and training into man's environment as related to his health and ecology.

P 11 Pharmacology-Toxicology Centers

An award for the establishment of a center for research and training made to an institution in the name of one or more investigators to provide long-term, stable support for studies relevant to the development of a rational basis for the safe and effective use of drugs. It may also serve as a regional or national resource for special purpose research, training, and service functions, and could involve the participation of several research institutions.

P 13 Dental Research Institute Program

To support the establishment and operation of centers of excellence for research and training in the sciences related to oral health.

P 15 Outpatient Clinical Research Program

To assist in the establishment, improvement and support of a research environment in which clinical studies of the causes, natural history, diagnosis, prevention and therapy of disease can be conducted.

P 16 Research and Demonstration Centers

For support of programs of multidisciplinary research, development, and demonstration with evaluation focused on a specific problem or modifying or creating new forms of prevention/detection/treatment/services, operating under controlled conditions, and evaluating the results against appropriate criteria.

Program Projects & Centers (Continued)

Code

P 17 Specialized Centers of Research

To focus resources, facilities, and manpower on particular problems and to expedite the development and application of new knowledge essential for improved diagnosis, treatment, and prevention of diseases.

P 18 Sickle Cell Centers

To focus resources, facilities and manpower in a coordinated attack on high priority sickle cell disease problems. In the setting of a Center, it should be possible to bridge the gaps between fundamental research, clinical applications, and demonstration community services programs, and to bring the results from any one component promptly to bear on the others.

P 20 Exploratory Grants

To support planning for new programs, expansion or modification of existing resources, and feasibility studies to explore various approaches to the development of inter-disciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers.

P 30 Core Center Grants

To support shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem. The core grant may support a specialized or comprehensive center and, though funded independently of the center's component projects or program projects, relates integratively to them. This support, by providing more accessible resources, is expected to assure a greater productivity than from the separate projects and program projects. Funds for the latter are obtained independently from the core.

P 40 Animal Resource Grants

To support animal resources available to all qualified investigators without regard to the scientific disciplines or disease orientations of their research activities or specifically directed to a categorical program area.

Program Project & Centers (Continued)

Code

P 41 **Biotechnology Resource Grants**

To support biotechnology resources available to all qualified investigators without regard to the scientific disciplines or disease orientations of their research activities or specifically directed to a categorical program area.

P 50 **Specialized Center**

To support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These grants differ from program project grants in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may be asked to perform additional studies on research problems because the funding component urgently needs information or to serve as a regional or national resource for special purpose research.

P 60 **Comprehensive Center**

To support a multipurpose unit designed to bring together into a common focus divergent but related facilities within a given community. It may be based in a university or may involve other locally available resources, such as hospitals, computer facilities, regional centers, and primate colonies. It may include specialized centers, program projects and projects as integral components. Regardless of the facilities available to a program, it usually includes the following objectives: to foster biomedical research and development both at the fundamental and clinical levels; to initiate and expand community education, screening, and counseling programs; and to educate medical and allied health professionals concerning the problems of diagnosis and treatment of a specific disease.

General Support (Research related)

Code

S 01 General Research Support

To provide flexible support of research and research training programs of qualifying institutions; to encourage these institutions to strengthen and to balance their health-related research activities in order to obtain a cohesive program. Either health professional schools or nonprofit research organizations engaged in health-related research may be supported. In this program each health professional school is considered to be an "institution" even though it may be a component of a university.

S 04 Health Sciences Advancement Award

To accelerate the advancement of existing capabilities in health research and related graduate research educational activities in institutions which have already demonstrated some achievement; to support advancement of new health research and training endeavors.

S 05 Biomedical Sciences Support Grant

To provide flexible support of research and research training programs of qualifying institutions; to encourage these institutions to strengthen and to balance their health-related research activities in order to obtain a cohesive program. Institutions of higher education, exclusive of health professional schools, engaged in health-related research may be supported.

S 06 Minority Biomedical Support - MBS

To strengthen the biomedical research and research training capability of ethnic minority institutions, and thus establish a more favorable milieu for the faculty and students in health-related sciences.

CONSTRUCTION

Code

C 05 Educational and Research Facilities Construction

To provide funds for the construction of new facilities or maintenance of existing facilities to further or continue educational and/or research program activities.

C 06 Cancer Research Facilities

To provide matching Federal funds, up to 75%, for construction or major remodelling, to create new cancer research facilities. In addition to basic research laboratories this may include, under certain circumstances, animal facilities and/or limited clinical facilities where they are an integral part of an overall cancer research effort.

TRAINING

Applied Training

A 02 Allied Health Professions Traineeship Grants for Advanced Training

To provide support to allied health professions personnel who are pursuing advanced training to prepare them to teach health services technicians or allied health professional personnel, to serve in administrative or supervisory capacities in the allied health professions, or to provide services in those allied health professions specialties that require such advanced training.

A 03 General Purpose Traineeship Grants to Schools of Public Health

To enable the schools of public health accredited by the American Public Health Association to award traineeships to students enrolled in the schools.

A 04 Special Purpose Traineeship Grants

To provide support to schools offering graduate or specialized training in public health in designated priority areas, from which awards are made by the school to enrolled students.

Applied Training (Continued)

Code

A 05 Public Health Nursing Traineeship Grants to Colleges and Universities

To enable schools of nursing accredited by the National League for Nursing to support up to 12 months of training leading to a baccalaureate degree to prepare registered nurses for first-level positions in public health nursing. Trainees must plan to enter a career in the field of public health nursing.

A 06 Traineeship Grants for Short-Term Training

To provide graduate or specialized short-term public health training for professional health personnel.

A 07 Traineeship Grants for Apprenticeship Training

To support a program intended to acquaint medical, osteopathic, and dental students with public health practice. Any public or non-profit private institution prepared to provide the proposed training is eligible to apply. Priority is given to institutions offering programs which reflect cooperation between an official health agency and departments of preventive medicine or dentistry, or a school of public health.

A 08 Residency Traineeship Grants in Preventive Medicine and Dentistry

To provide support to institutions and agencies with nationally approved residency programs in General Preventive Medicine, Preventive Medicine - Public Health, and Dental Public Health. It is intended to encourage physicians and dentists who have completed their basic professional training to prepare for positions of leadership in public health practice and teaching.

A 10 Environmental Health Traineeship Grants

For the support of traineeship at any school or department in an accredited college or university in the United States conducting a graduate training program in environmental health.

Applied Training (Continued)

Code

A 11 Professional Nurse Traineeship Program (long-term)

To increase the number of graduate nurses training on a long-term basis for positions as administrators, supervisors, nursing specialists, and teachers in hospitals and related institutions, public health agencies, and schools of nursing.

A 12 Professional Nurse Traineeship Program (short-term)

To increase the number of graduate nurses training on a short-term basis for positions as administrators, supervisors, nursing specialists, and teachers in hospitals and related institutions, public health agencies, and schools of nursing.

A 13 Allied Health Professions Grants for Training Institutes

To provide support to public or non-profit private agencies, organizations, and institutions for the support of post-professional training programs of less than an academic year to prepare or expand the teaching capabilities of allied health professionals, prepare or expand the capabilities of allied health professionals for leadership roles such as administrators or supervisors to assume broader functions, and to prepare allied health professionals to specialize in an area within their respective fields.

A 14 Occupational Safety & Health Professions Grants for Training Institutes - Short-Term

To provide specialized short-term training for upgrading the competency of professional and technical personnel engaged in the field of oocupational safety and health.

A 15 Grants for Training and Traineeships for Health Professions Teaching Personnel

To provide support to schools of medicine, dentistry, osteopathy, podiatry, optometry, pharmacy, and veterinary medicine for training (at such schools or elsewhere) and traineeships for the advanced training of individuals to enable them to teach, or improve their teaching skills, in the health professions fields. At least 75 percent of any grant under this program must be used for traineeships.

Training Program Projects

Code

D 01 Allied Health Professions Special Improvement Grants

To assist in the provision, maintenance, or improvement of the specialized functions served by centers in educating and training Allied Health Professions personnel.

D 02 Developmental Grants

To develop, demonstrate, or evaluate curriculums for the training of new types of health technologists; new methods of training known types of health technologists; curriculums designed to reflect the expanded scope of functions of, or the regrouping of selected duties currently performed in, or otherwise resulting from, modification of an existing specialty's or occupation's defined set of functions, duties, responsibilities, and skills; instructional techniques and/or methods for the training of health technologists.

D 04 Project Grants for Graduate Training in Public Health

To strengthen or expand graduate public health training in eligible schools of public health, nursing, and engineering; graduate program in hospital administration; and departments of preventive medicine and dentistry in schools of medicine, osteopathy, and dentistry. These grants are made to assist such schools in improving and enriching their curriculums to meet the needs of changing and emerging public health programs; in strengthening programs of basic training in public health administration; in developing and demonstrating public health training methods to provide for increased enrollments.

D 06 Dental Auxiliary Utilization Program

To assist schools of dentistry in establishing programs to training dental students in the effective utilization of dental auxiliary personnel.

Code

D 07 Continuing Education Training Program

To assist schools of dentistry and other public non-profit institutions, organizations, and agencies in establishing programs of continuing education for dentists.

D 08 Health Professions Special Project Grants

To assist schools of medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, and podiatry in carrying out special projects for 13 various purposes specified by enabling legislation.

D 10 Nursing Special Project Grants

Grants may be made to assist any public or non-profit private agency, organization, or institution to meet the costs of special projects to plan, develop, or establish new programs or modifications of existing programs of nursing education or to effect significant improvements in curriculums of schools of nursing or for research in the various fields of nursing education; to assist in otherwise strengthening, improving, or expanding programs of nursing education or to assist any such agency, organization or institution to meet the costs of other special projects which will help to increase the supply of adequately trained nursing personnel.

D 11 Dental TEAM Program

To teach dental students to manage and supervise a total dental health team which includes various types of auxiliaries with expanded functions, to teach dental students auxiliary utilization procedures related to improving dental health care delivery systems; to support experimentation relating to auxiliary utilization leading to training the dental student to function in an improved system of care delivery, and to train auxiliaries with expanded functions, when necessary, to achieve the above.

D 12 Allied Health Professions Special Projects Grants

To provide support to public or non-profit private agencies, organizations, and institutions to plan, establish, demonstrate or develop: new programs, programs to reach special groups (e.g., returning veterans with experience in the health field, economically or culturally deprived persons reentering allied health occupations), interrelationships among institutions to facilitate training, retraining, or utilization of allied health manpower. Objectives are also to modify or expand existing programs, including inter-disciplinary training programs to develop, demonstrate, or evaluate:

Training Program Projects (Continued)

Code

D 12 Allied Health Professions Special Projects Grants (Cont'd.)

new or improved teaching methods or curriculums, new types of health manpower, techniques for appropriate recognition (including equivalency and proficiency testing mechanisms) of previously acquired training or experience, and developing, demonstrating, or evaluating new or improved means of recruitment, retraining, or retention of allied health manpower.

D 14 Grants to Assist Health Professions Schools in Financial Distress

To assist any school of medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, or podiatry which is in serious financial straits to meet its costs of operation or which has special need for financial assistance to meet accreditation requirements.

D 15 Grants for Training in Family Medicine

To provide support to public or nonprofit private hospitals to plan, develop, and operate an approved professional training program in the field of family medicine. Funds may be awarded for the expansion and improvement of approved residency training programs in family medicine and for the support of residents in family medicine.

D 16 Grants for Start-Up Assistance

To provide start-up assistance to medical, osteopathic, dental, and nursing schools to assist in meeting the costs of planning, developing, or initiating new programs.

D 17 Nursing Financial Distress Grants

To assist public or nonprofit private schools of nursing which are in serious financial straits to meet operational costs required to maintain quality educational programs or which have special need for financial assistance to meet accreditation requirements.

Training Program Projects (Continued)

Code

D 18 Special Health Career Opportunity Grants

To identify and increase admissions to and enrollment in schools of medicine, dentistry, osteopathy, optometry, podiatry, pharmacy, veterinary medicine, public health, or other health training of individuals whose background and interests make it reasonable to assume that they will engage in the practice of their health profession in rural or other areas having a severe shortage of personnel in such health profession and to identify individuals with a potential for education or training in the health professions who due to socioeconomic factors are financially or otherwise disadvantaged to undertake such post-secondary education or training as may be required to qualify them to enroll in such a school.

D 19 Grants for Utilization of Nursing Educational Talent

Grants for Utilization of Nursing Educational Talent - to identify individuals with a potential for nurse training and encourage such individuals to undertake professional nurse training or become qualified to undertake such training and to establish programs to enhance and facilitate the enrollment of identified individuals.

D 20 Health Sciences and Computer Technology

To promote the complete and effective integration of computer technology into all phases of clinical medicine - teaching, practice and research.

D 21 Health Manpower Education Initiative Projects

To provide assistance to public or nonprofit private health or educational entities for projects to improve the distribution, supply, quality, utilization, and efficiency of health personnel and the health services delivery system.

D 22 Grants to Assist District of Columbia Medical and Dental Schools

To assist private nonprofit medical and dental schools in the District of Columbia in their critical financial needs to meet operational costs required to maintain quality educational programs and to increase the number of students. Grants are awarded to the Mayor of the District of Columbia for the beneficiary schools.

General Support (Educational)

Code

E 02 Formula Grants to Schools of Public Health

To support the provision of public health training and to help offset the cost of training Federally-sponsored students at accredited schools of public health. The grant funds may be used for support of faculty and administrative personnel, equipment, supplies, and travel, continuation education, and other costs of operating the training programs of the schools of public health.

E 03 Health Professions Capitation Grants

To provide a dependable support base for the educational programs of schools of medicine, osteopathy, dentistry, veterinary medicine, optometry, pharmacy, and podiatry. These grants may be used for any purpose which each school judges will contribute to its educational program except: construction, financial assistance to students, research or patient care not necessary for the educational program of the school, hospital bed costs, operating deficits of teaching hospitals, and other costs not integral to the education of students.

E 04 Nursing Capitation Grants

To provide a dependable support base for the educational programs of schools of nursing. These grants may be used for any purpose which the school judges will contribute to its educational program except: construction, financial assistance to students, research or patient care not necessary for the educational program of the school, hospital bed costs, operating deficits of teaching hospitals, and other costs not integral to the education of students.

E 06 Grants for Conversion of Two-Year Schools of Medicine

To provide support to two-year schools of medicine which intend to become schools accredited to grant the degree of doctor of medicine. Schools must apply before July 1, 1974, and enroll third-year students not later than the 1974-1975 school year. No school may receive more than one grant under this program.

E 07 Categorical Education Grants

To provide educational and training programs primarily for the prevention of categorical diseases.

Fellowships

Code

F 01 Predoctoral Fellowships

To provide predoctoral research training support in health and health-related areas to holders of baccalaureate degrees or equivalent experience. Fellowships are not awarded for study leading to the M.D., D.O., D.D.S., D.V.M., or other applied science degrees. An institutional allowance of $2,500 is normally provided to a sponsoring institution in the United States in lieu of tuition and all other fees.

F 02 Postdoctoral Fellowships

To provide postdoctoral research training support in health and health-related areas to individuals having received a Ph.D., M.D., D.D.S., D.O., D.V.M., Sc.D., D.Eng., or equivalent domestic or foreign degree. A supply allowance of up to $1,000 ($500 for U. S. Government Labs) per 12-month period will be provided, upon request, to the sponsoring institution.

F 03 Special Fellowships

To provide support for individuals in mid-career to extend their potential for research in health and health-related areas. To be eligible one must (1) have a doctorate or equivalent degree and at least 3 subsequent years of relevant research or professional experience, or (2) have completed residency requirements in a medical specialty, or (3) have otherwise demonstrated to the PHS sufficient competence in their field to pursue the proposed training program, or (4) have graudated from a school of nursing and have a baccalaureate degree (for professional nurse applicants). A supply allowance of up to $1,000 ($500 for U. S. Government Labs) per 12-month period will be provided, upon request, to the sponsoring institution.

F 04 Nursing Fellowships

To provide support to graduates of professional schools of nursing under the Special Fellowships Program (F 03) for predoctoral and postdoctoral research training in health and health-related areas.

F 05 International Fellowships

To support the training of qualified non-immigrant alien scholars who hold a Doctoral Degree or its equivalent in a health-science field.

Fellowships (Continued)

Code

F 06 Senior International Fellowships

To provide opportunities to outstanding mid-career faculty members from U. S. schools of medicine, osteopathy, dentistry, and public health with demonstrated productive scholarship and recognized stature in their profession to go abroad to study and share their expertise.

F 09 Scientific Evaluation

To provide the chairman of a fellowship review committee funds for the operation of the review group.

F 10 Fellowship Traineeship

A special fellowship application logged and reviewed as F 03 but changed to F 10 by NINDS for research training in health and health-related areas.

F 12 Medical Scientist Fellowships

To provide combined M.D.-Ph.D. training to outstanding individuals nominated by medical schools that do not have Medical Scientist Training Grants.

F 14 MARC Faculty Fellowships

To provide special fellowships to selected faculty members from minority institutions to enable them to obtain advanced training in research and the biomedical sciences.

F 15 Fogarty International Scholarships

To facilitate the exchange of ideas among distinguished science leaders and scholars who will spend from 3 to 12 months in residence at NIH.

F 16 MARC Visiting Scientist Fellowships

To provide special fellowships to visiting scientists who are interested in going to minority institutions to help them develop their research and academic programs in the biomedical sciences.

Fellowships (Continued)

Code

F 17 Clinical Fellowship Program

To increase the number of trained professional people who have special interest and capabilities in disease management and who will serve their patients and colleagues and their communities in the prevention, diagnosis, therapy, and control of diseases.

F 22 Individual Research Fellowships

To broaden scientific background for research training in specified shortage areas, and to extend potential for research in health-related areas.

F 31 Predoctoral Individual National Research Service Award

To provide predoctoral individuals with supervised research training in specified health and health-related areas leading toward the research degree (e.g., Ph.D.).

F 32 Postdoctoral Individual National Research Service Award

To provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health related areas.

Research Career Program Awards

K 01 Research Scientist Development Award - Research & Training

For support of a scientist, committed to research, in need of both advanced research training and additional experience.

K 02 Research Scientist Development Award - Research

For support of a scientist, committed to research, in need of additional experience.

K 03 Research Career Development Awards

To enhance the career development of outstanding scientists with clear research potential or demonstrated capacity for independent research who require additional training and experience in a productive scientific environment in preparation for careers in independent research. This applies only when the application for the initial award was received before July 1, 1967.

Research Career Program Awards (Continued)

Code

K 04 Modified Research Career Development Awards

To foster the development of young scientists with outstanding research potential for careers of independent research in the sciences related to health. This applies only when the application for the initial award was received after July 1, 1967.

K 05 Research Scientist Award

For the support of a research scientist qualified to pursue independent research which would extend the research program of his sponsoring institution, or to direct an essential part of this research program.

K 06 Research Career Awards

To enable institutions to finance positions favorable to the intellectual growth and research productivity of established investigators of high competence for the duration of their careers.

K 07 Academic Career Award

To create and encourage a stimulating approach to disease curricula that will attract high quality students, foster academic career development of promising young teacher-investigators, develop and implement excellent multidisciplinary curricula through interchange of ideas and enable the grantee institution to strengthen its existing teaching program.

K 08 Clinical Investigator and Faculty Development Award

To provide the opportunity for promising medical scientists (with demonstrated aptitude to develop into independent investigators) or faculty members who will pursue research aspects of categorical areas applicable to the awarding unit, and aid in filling the important academic faculty gap in these shortage areas within health professional institutions of the country.

K 09 Scientific Evaluation

To provide the chairman of the review committee funds for the operation of the review group.

Research Career Program Awards (Continued)

Code

K 10 Special Scientific Projects

To facilitate the utilization and to increase the understanding of recorded information in fields related to health; the program enables qualified individuals to devote a period of full-time effort to the scholarly documentation, evaluation, and analysis of social, cultural, or scientific advances in various fields, disciplines, or specialties of the health sciences.

Research Training

T 01 Graduate Training Programs

To assist and extend training of individuals preparing for research and academic careers in fundamental, preclinical, clinical, public health, and other disciplines related to the area of interest of the awarding Institute/Division.

T 02 Undergraduate Training Programs

To assist qualified institutions to improve and expand the training of undergraduate students in disciplines related to the area of interest of the awarding Institute/Division.

T 05 Medical Scientist Training Programs

To assist universities and their medical schools in the development of broad, institutionally based programs that provide carefully selected trainees the essential scientific and medical background needed for a career as a medical scientist. (A medical scientist differs from most basic scientists in having had the medical training required to investigate problems of disease in man.)

T 07 Program for Experimental Training for Clinical Investigation

To support individually programmed training programs by departments of medicine or other clinical departments for new and imaginative methods of early identification and training of future clinical investigators and academicians.

T 09 Scientific Evaluation

To provide the chairman of the training committee funds for operation of the review group.

Research Training (Continued)

Code

T 10 Hospital Staff Development Program

To initiate, expand, and improve the quality of staff development and training programs in state mental hospitals and institutions for the mentally retarded.

T 14 Conferences

For support of international and national meetings, conferences, and workshops.

T 15 Continuing Education Training Grants

To assist professional schools and other public and non-profit institutions to establish, expand, or improve programs of continuing professional education, especially for programs of extensive continuation, extension, or refresher education, dealing with new developments in the science and technology of the profession.

T 17 Development Training

To support institutions with strong programs in research and biomedical sciences in providing training for faculty members from institutions wishing to strengthen their academic programs.

T 21 Pilot Projects

To develop and evaluate training methods and programs for certain specific types of projects in the area of mental health. They must be exploratory, innovative, and experimental.

T 22 Institutional Research Fellowships

To support an institution with an approved preceptor for a number of postdoctoral research training fellowships in a limited number of specified shortage biomedical science areas.

T 31 Special Projects

To support various types of training activities, such as demonstrations, surveys, institutes, or workshops, in the field of mental health.

Research Training (Continued)

Code

T 32 Institutional National Research Service Award

To enable institutions to make to individuals selected by them National Research Service Awards for predoctoral and postdoctoral research training in specified shortage areas.

T 41 Utilization and Development

To continue specific pilot projects as well as other training projects not previously supported by NIMH; to replicate specific projects; to conduct projects of recruitment; and to convene workshops, etc., concerned with dissemination and utilization of information derived from pilot training projects.

FOREIGN CURRENCY

W 01 Special Foreign Currency (PL 480) Program

To support, through utilization of U.S.-owned foreign currencies, overseas scientific activities within the program interests of the NIH and of mutual interest to the cooperating foreign country.

AGREEMENTS

Y 01 Interagency and Intraagency Agreements

To include, but not limited to, arrangements for the receipt or giving of services, supplies, advice and counsel. An arrangement between an NIH component and one or more Federal agencies outside the DHEW is known as Interagency Agreement. When the arrangement is between an NIH component and another DHEW organization, the arrangement is known as an Intraagency Agreement.

OTHER GENERAL SUPPORT

G 01 Medical Library Resource Grant Program

To expand and improve the basic medical library or related resources of public and private non-profit institutions.

Research Training (Continued)

Code	
G 04	Regional Medical Library Grant Program To assist in the development of a national system of regional medical libraries, each of which would have facilities of sufficient depth and scope to supplement the services of other medical libraries within the region served by it.
G 07	Resources Improvement Grant A one-year, nonrenewable grant to establish a library or expand or improve present libraries which have inadequate resources relative to their needs and user population.
G 08	Resources Project Grant A grant available for institutions with medical libraries which meet minimal standards in terms of staff, collection, and institutional support and who propose a plan for the improvement of services as opposed to the acquisition of basic resources.

CONTRACTS

Code	
N 01	Research and Project Contracts To develop and/or apply new knowledge or to test, screen, or evaluate a product, material, device, or component for use by the scientific community.

HEALTH SERVICES

Code	
H 84	Prevention, Treatment, and Rehabilitation Grants To provide programs and services for rehabilitation, prevention, and treatment of categorical diseases.

APPENDIX D

Special Grants and Awards Programs
# of the
National Institute of General Medical Sciences

The National Institute of General Medical Sciences

Grants and Awards Programs

DISCRIMINATION PROHIBITED--Title VI of the Civil Rights Act of 1964 states: "No person in the United States shall, on the ground of race, color, sex, age, or national origin, be excluded from participation, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance." Therefore, the grant and award programs of the Public Health Service, like every program or activity receiving financial assistance from the Department of Health, Education, and Welfare, must be operated in compliance with this law.

INTRODUCTION

The National Institute of General Medical Sciences supports research and research training in the basic or general biomedical sciences which have significance for two or more institutes or are outside the general area of responsibility of any other institute.

Institute activities are organized and conducted through its five operating programs: Cellular and Molecular Basis of Disease, Genetics, Pharmacology-Toxicology, Clinical and Physiological Sciences and Biomedical Engineering. Interprogram cooperation is stressed because projects and developments in one program frequently are relevant and of consequence to others. Each program fosters and supports multidisciplinary approaches and resources, employing the full range of support mechanisms--research project grants, program-project grants, research center grants, career development awards, and institutional and individual fellowships. Additionally, contracts are let to achieve specified objectives in collaboration with government laboratories, industrial organizations or nonprofit institutions, resulting from either solicited or unsolicited proposals.

CELLULAR AND MOLECULAR BASIS OF DISEASE PROGRAM

This program is devoted to greater understanding of the function of human cells in terms of ultrastructure, with the basic premise that many forms of human disease occur ultimately as the direct result of disturbed or abnormal function of cells. Investigations receiving support are broadly concerned with the biophysical and biochemical description and analysis of molecular events in normal and diseased cells, and the structure and function of cell organelles and membrane processes at molecular and subcellular levels. Areas of research emphasis include: (1) detailed submolecular structure and function of enzymes, other proteins, and other biological substances; (2) development of knowledge of subcellular organelles and their constituents into more precise concepts of how the cell functions as a unit; (3) cell-cell interactions during morphogenesis; (4) mechanisms by which enzymes bring about their catalytic effects; (5) elucidation of the relationship between chemical structure and biological activity.

Molecular Pathology Centers

These centers are conceived as bringing together, under the focus of a general pathologic problem, several basic medical science disciplines and approaches in the study of disease.

The past two decades have provided a new set of ideas and instruments for the study of disease at the subcellular and molecular levels of organization. Many of these advances have resulted from basic biologic research on subcellular structures such as lysosomes, mitochondria, microtubules, and membranes. Pathologists now are able to identify structural and biochemical changes at the subcellular and molecular levels that are characteristic of specific diseases. The new program of Molecular Pathology Centers seeks to promote increased collaboration among pathologists, biochemists, biophysicists, electron microscopists, and other scientists investigating related subcellular phenomena in more quantitative molecular terms. This is expected to enhance and speed our understanding of the cellular and molecular basis of disease.

Program Contact: Program Director, Westwood Building, Room 903

GENETICS PROGRAM

This program is directed toward gaining a better understanding of the fundamental processes and mechanisms of inheritance in health and disease. Its objectives are the prevention and improved treatment and care of genetic ills in man, including multifactorial diseases with a strong hereditary component, such as diabetes, atherosclerosis, hypertension, and schizophrenia. The various categorical NIH institutes appropriately consider the treatment of individual diseases as discrete problems requiring a specific approach and resolution. In contrast, the NIGMS Genetics Program attempts to exploit broadly strategic research opportunities which may yield generalizable concepts. Supported research ranges from studies on nucleic acid chemistry to population genetics. Topics include the organization, transmission, and expression of genetic information. Lower organisms, such as bacteria, are used as model systems for the elucidation of basic genetic principles. At the other end of the spectrum, the techniques of mammalian cell culture are being exploited for the mapping of human genes and for the study of the basic biochemical defects underlying human genetic diseases. Also of concern are the legal, social, and moral implications of new genetic knowledge, such as assessment of the effects and effectiveness of genetic counseling.

Genetics Research Centers

This center program was established to foster interaction among scientists involved in basic and clinical research. In these centers, research in human genetics has been greatly facilitated by the availability of patients for study and a setting in which research findings can be clinically evaluated. New ideas and progress are engendered by familiarization of basic scientists with specific human genetic problems. The concept includes basic laboratory investigation and clinical genetics support as each relates to the overall goals.

Program Contact: Program Director, Westwood Building, Room 918

PHARMACOLOGY-TOXICOLOGY PROGRAM

The world we live in is dominated by drug actions and reactions, if drugs are defined broadly as non-food chemicals--therapeutic and non-therapeutic. The objective of the Pharmacology-Toxicology Program is to deal primarily with therapeutic drugs. The program ranges in scope from the synthesis of new drugs, to basic studies on the molecular and cellular mechanisms of action, to rigidly controlled clinical studies in man. Support is provided for research on the absorption, metabolism, distribution, and excretion of drugs in man; on factors influencing bioavailability; and on the development of improved surveillance of adverse reactions to drugs. The program also provides support in the area of medicinal chemistry, which broadly includes the chemistry of natural products, chemical aspects of biological processes, the relationship between chemical structure and biological activity, and chemical methodology. Increasing emphasis is being placed on clinical, especially pediatric, pharmacology and on the development of new methodology and analytical techniques.

Pharmacology-Toxicology Research Centers

University-based centers in pharmacology-toxicology provide discrete central research facilities and resources, at the core of which are teams of basic research scientists, pharmacologists, toxicologists, medicinal chemists, and physicians who investigate problems relating to rational pharmacotherapeutics, cutting across all disease categories. This network of centers creates a unique national resource for the development of knowledge concerning the safety and efficacy of drugs and the ultimate application of this knowledge to the treatment of diseases in man.
Program Contact: Program Director, Westwood Building, Room 9A05

CLINICAL AND PHYSIOLOGICAL SCIENCES PROGRAM

The goal of this program is to strengthen the scientific base of those areas of clinical science for which the Institute is responsible in order to improve patient care. Support for coordinated basic and clinical investigations relating to trauma and burn research and to anesthesiology is intended to foster a more rapid application in clinical practice of new knowledge gained from research in such areas as cell biology, physiology, biochemistry, pharmacology, behavioral sciences, and bioengineering. Trauma and burn research is directed to the discovery of better ways to prevent death from injury, mitigate pain, speed recovery of patients and lessen the extent of disabilities caused by injuries. A better understanding of the total body response to trauma is sought. This includes the biochemical and physiological changes induced by trauma, and the fundamental aspects of wound healing and biological repair. Emphasis is also given to research on the treatment of post-traumatic infections, the nutritional requirements of convalescing victims, and rehabilitation of injured patients. Research in anesthesiology is concerned with the mode of action of anesthetics and muscle relaxants, the nature and control of pain, basic physiologic and metabolic changes resulting from anesthesia, the management of respiratory failure, obstetrical and neonatal resuscitation, handling of postoperative respiratory complications, and the pulmonary and systemic effects of drowning. Support is also provided for studies in epidemiology, and in behavioral sciences related to trauma and analgesia.

Trauma and Burn Research Centers

In severe trauma, the injury results in the breakdown of the normal protective barriers leading to sepsis and sequential organ failure. The search for better methods of resuscitation depends on a better understanding of the mechanisms of injury and of the compensatory physiological and biochemical processes.

These multidisciplinary centers currently are involved in studies on energy exchange and metabolism, cellular and subcellular changes in shock, pulmonary physiology and patient monitoring, endocrine responses, sepsis, and burns. Although each of the centers uses a different approach to the study of trauma, they all:

- . perform basic laboratory investigations which may be brought to the bedside for immediate clinical application, and
- . provide the environment for active teaching and training in the care of severely injured patients.

Anesthesiology Research Centers

The anesthesiology research centers encompass both basic and clinical research on the uptake, distribution, and mode of action of anesthetic agents, relief of pain, the management of respiratory failure, resuscitation, and intensive care. The centers foster closer collaboration between pharmacologists, physiologists, and anesthesiologists and seek to broaden the scientific base of anesthesiology.

Program Contact: Program Director, Westwood Building, Room 925

BIOMEDICAL ENGINEERING PROGRAM

This program encourages and supports the application of engineering knowledge to problems in fundamental and applied biomedical research, directed in part to the development of new instruments and devices useful in medicine and health services delivery. In the latter instance, objectives are to advance and automate clinical laboratory analytical processes and to improve diagnostic radiology techniques for locating and characterizing altered body processes and structures emphasizing such measures as ionizing radiation, radioisotopes, thermography, and ultrasound. More basic goals are to enhance the exploration of life processes at molecular levels, and to apply engineering control theories to studies of physiological processes. Development of microelectronic instrumentation for research and patient care purposes is encouraged, as is the use of computer technologies in medical data processing and clinical decision making. This work encompasses the development of new systems for data acquisition and display involving new types of transducers and integrated circuitry, and the development and application of mathematical models of physiological systems to predict more accurately and rapidly the clinical status of acutely ill patients. Research in areas of biomechanics and biomaterials is also supported.

Biomedical Engineering Research Centers

Over the next several years the Institute will gradually undertake a grant-supported program of biomedical engineering research centers to exploit further the growing relationship between engineering, biology and medicine. Over the next five years it is expected that some six to ten centers will be established.

It is anticipated that: (1) these centers will usually be multidisciplinary and multidepartmental; in some instances they will stimulate the evolution of new linkages and institutional forms between engineering and medical schools; (2) they will represent a scientific focus (as instrumentation research and development, biomaterials, biomechanics) in which there will be a cluster of problems which can be defined and to which solutions are being sought; (3) they may serve as regional foci for special-purpose research and development.

With the passage of time, it is intended that these centers will provide a continuing assessment of the areas of greatest potential for the application of engineering concepts and practice to biomedicine.

Diagnostic Radiology Research Centers

In these centers, special attention is given to the development of instrumentation in radiation and nuclear medicine to improve the sensitivity, selectivity, and accuracy of diagnosis and treatment.

Research performed within the centers includes studies using ionizing radiation, radioactive isotopes, infrared radiation, thermography, or ultrasonic techniques for the investigation of structure and function in disease. Another area of interest is the development and evaluation of new diagnostic equipment and contrast agents. The radiologic examination itself is being analyzed as to efficiency in diagnostic techniques and methods of reporting results.

Program Contact: Program Director, Westwood Building, Room 957

Minority Access to Research Careers (MARC) Program

Special fellowships are provided under this program to improve the research training and increase the number of minority group biomedical scientists. MARC Faculty Fellowships are awarded to selected full-time faculty members of four-year colleges, universities, and health professional schools in which student enrollment is drawn substantially from ethnic minority groups. Applicants must be nominated by their institutions and are expected to return to do research and teach at the sponsoring institution after completion of the fellowship. Another type of support is the MARC Visiting Scientist Fellowship, awarded to assist outstanding scientist-teachers to serve in the capacity of visiting scientists at eligible minority institutions.

The MARC Program, which is being administered in collaboration with the National Cancer Institute, complements the Minority Biomedical Support (MBS) Program of the NIH Division of Research Resources in which funds are granted directly to minority institutions to strengthen both bioscience faculties and teaching facilities.

Program Contact: Program Director, Westwood Building, Room 9A18

JAN 1976

APPENDIX E

Special Programs Designed to Stimulate Manpower Developments in Special Areas of Need

MINORITY ~~SCHOOLS~~ BIOMEDICAL SUPPORT PROGRAM

General Policy and Information Statement

U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Public Health Service
National Institutes of Health

December 1971

MINORITY SCHOOLS
BIOMEDICAL SUPPORT PROGRAM

General Policy and Information Statement

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
USA

An Administrative Document
Issued by
General Research Support Branch
Division of Research Resources
National Institutes of Health
Bethesda, Maryland 20014

MINORITY SCHOOLS BIOMEDICAL SUPPORT PROGRAM

General Policy and Information Statement

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GENERAL POLICY AND INFORMATION STATEMENT

I. INTRODUCTION

Under the authority of Section 301(d) of the Public Health Service Act, as amended [42 U.S.C. 241(d)], the General Research Support Branch, Division of Research Resources, National Institutes of Health, has initiated the Minority Schools Biomedical Support (MSBS) program; this program is designed to strengthen the institutional research and research training capability of four-year colleges, universities, and health professional schools in which student enrollments are drawn mainly from ethnic minority groups (such as blacks, browns, reds, and orientals).

The MSBS program is deemed necessary in order that minority institutions shall have equality of opportunity to participate in biomedical research. Additionally, the MSBS program is intended to encourage increased involvement of students at minority institutions in the biomedical sciences and in medicine, dentistry, and other health professions.

The Minority Schools Biomedical Support program is consistent with the clear mandate expressed by the President of the United States in his message to Congress proposing measures to "Expand Opportunities for Higher Education" (February 22, 1971):

> ". . . . Black institutions are faced with a historic inadequacy of resources. To help these institutions compete for students and faculty with other colleges and universities, the combined help of government at all levels, other institutions of higher learning, and the private sector must be summoned . . . ."

The Congress also expressed a mandate for this type of award program. The Senate Appropriations Committee called for the National Institutes of Health, Division of Research Resources, General Research Support Branch (GRSB), to initiate a program for black colleges in fiscal year 1972. The Labor-DHEW Appropriations Bill, as enacted by both Houses of Congress, retained the budget level set by the Senate for the GRSB program, thereby ratifying the words of the Senate Appropriations Committee: [1]

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[1] Senate Appropriations Committee Report, No. 92-316, July 29, 1971

> "The Committee . . . . encourages the General Research Support Branch to initiate a program for the development of the health sciences at predominantly black colleges which have been unable to provide adequate preparation for definitive training in health research fields and the health professions. Since historically black students have not had equality of opportunity to become investigators in health research fields and to become physicians, dentists, and other health professionals, chiefly due to a lack of adequate research and teaching facilities and the inability of black institutions to compete for sufficient numbers of professionals, it is incumbent upon the Federal Government to rectify these inequalities."

While the above statements address themselves primarily to the importance of developing and implementing a meaningful program for blacks, other ethnic minorities are in much the same position. Accordingly, the MSBS program called for by the Presidential and Congressional mandates will include these other groups as well.

II. PROGRAM GOAL AND USES OF THE MSBS AWARD

A. Goal

The goal of the MSBS program is to strengthen the biomedical research and research training capability of minority institutions, and thus establish a more favorable milieu for the faculty and students in health-related sciences.

Biomedical research is defined here as those scientific investigations undertaken in areas related directly or indirectly to health and health problems. The research is frequently carried out by physicians, dentists, veterinarians, pharmacists, and biologists. However, NIH supports biomedical research conducted by psychologists, chemists, physicists, mathematicians, engineers, ecologists, and other scientists and health professionals. Thus, biomedical research may be conducted in any applicable science or health professional department at an academic institution.

B. Uses of the MSBS Award

Recognizing that this is a new program to strengthen biomedical research and research training in health-related sciences of ethnic minority institutions, opportunity is provided for the ingenuity and creativity of the applicants to be exercised.

The following are some of the ways in which MSBS funds may be used by institutions:

1. Support for Faculty "Released Time"

   ... Salaries for time or effort involved in research and/or research training, as a substitute for a portion of teaching responsibilities. To maintain the quality level of the teaching programs, the institution is expected to use the released teaching salaries for other faculty members (possibly new) to assume the teaching responsibilities.

2. Support for Biomedical Research Projects

   ... Special summer projects

   ... Initiation, expansion, and continuation of full-scale and pilot projects

   ... Cooperative research projects between investigators in several disciplines (such as chemistry and biology, for example)

   ... "Seed" funds for promising biomedical research ideas or support of exploratory research (The purpose of such support is to offer an opportunity to investigators to extend their theories and techniques into the field of biomedical research. The intent is to encourage the development of biomedical research ideas which should lead to or form the basis for the development of more formal research applications.)

   ... Funds for equipment, supplies, travel, publication costs, and other necessary costs related to research

3. Support for Research Personnel

   ... Salaries of undergraduate and graduate students as research assistants and laboratory technicians

   ... Faculty training expenses

   ... Faculty recruitment and "Visiting Scholars-in-Residence" programs

- ... Salaries of postdoctorals, research professors, technical personnel, consultants, and research secretaries

4. Support for Research Training Programs

- ... Stipends, tuition, and dependency allowances for undergraduate, graduate, and postgraduate trainees
- ... Costs of the training environment, e.g., faculty salaries, consultants, technical assistance, equipment, travel, publication costs, supplies, etc.
- ... Summer training experiences for undergraduate and graduate students
- ... Special research project courses, such as college senior research training courses

5. Support for Research Resources

- ... Costs directly related to the establishment and operation of central research resources, such as computer centers, animal facilities, instrument shops, etc.
- ... Departmental and institutional purchase of equipment and supplies for research
- ... The renovation of facilities for research

6. Support for Consortia

- ... Smaller schools sending students to a larger institution for summer biomedical research or research training
- ... Cooperative seminars and biomedical workshops by schools in the same area
- ... The use of one school in a given locale for research and/or research training in one discipline such as chemistry, another institution for a second discipline such as biology, and still another college for other disciplines such as physics or psychology - to utilize more efficiently professional staff, space, and research equipment.
- ... Cooperative seminars and programs involving eminent scholars

The above are only examples of uses to which MSBS funds may be directed. Other proposed uses are encouraged to be included in the MSBS application.

III. NATURE AND SIZES OF MSBS PROGRAMS

Minority Schools Biomedical Support (MSBS) awards are available to four-year colleges, universities, and health professional schools within the United States and its territories that are ethnic minority schools.

A. Types of MSBS Proposals

Each institution should seek MSBS support for those biomedical research and research training activities that will contribute most cogently to the overall advancement of the institution. Since research is a much more significant aspect of the environment of some institutions than of others, MSBS proposals will vary greatly. Moreover, it can be expected that an institution will take one of the following three approaches:

1. First Approach

An institution may decide that its role in biomedical research is rather modest and that the best interests of the institution are served by support of individual faculty members in one or more science departments. As an example, research interested professors with heavy teaching loads can be provided with released time salary support to carry out research programs.

Existing equipment can be supplemented and supplies purchased. Furthermore, salary support can be provided for laboratory assistants who may be chosen from among science-oriented college students.

The institution should be motivated in its selection of one or more individualized programs because of the benefits derived to the institution, its faculty, and its students. Thus, in the example cited, a number of research activities would diversify the institution's programs. Also, the faculty members, by engaging in research and attending related professional meetings, would more easily keep abreast of their scientific fields and this should strengthen the content of their courses.

Equipment obtained for research purposes could also be used by students in their special research courses, thereby opening up new types of research projects to them. Students employed as laboratory assistants would obtain financial aid, and more importantly they would be getting an introduction into the world of biomedical research which would motivate their selection of future careers as scientists or health professionals. Another considerable value to be derived would be the opportunity for the institution to expand its teaching faculty by use of the teaching salary funds released by the MSBS program.

Grants to institutions using this approach may well range from $150,000 to $250,000 over a five-year period, depending upon the number of professionals involved in the program.

2. Second Approach

In other institutions research and research training may be a more significant activity. Consequently, an institution may identify a department or other cohesive institutional element where, faculty and students have a greater involvement in research, and where, for example, students undertake programs of study which include research as an important curricular requirement.

In such a case, where a stronger interest and capability exist, the institution could use MSBS funds in a coordinated program across a department, involving a large proportion of the faculty in research programs of diversity and depth so that the general research environment would be strengthened. Students working in collaboration with their professors (rather than as laboratory assistants only) would be able to explore new biomedical research techniques using advanced equipment. Moreover, because faculty research salary support could be employed, the teaching funds released and the MSBS research salary funds available could allow the institution to recruit new faculty members with strengths in disciplines not previously represented. In this way, greater balance and breadth would be achieved within a department.

Grants to institutions sufficiently involved in biomedical research to choose this approach may well range from $500,000 to $750,000 over a five-year period.

3. Third Approach

In still other institutions, biomedical research may be broadly significant to the institution, either throughout the entire institution or within one or more schools or within several large departments. Faculty involvement in research, for example, would be widespread, so that the normal teaching load would be proportionately smaller than in many other institutions. Students are likely to be actively and deeply engaged in research as a necessary component of their training and development.

Here an institution could develop a broad plan for the use of MSBS funds throughout many components of the institution, and to considerable depths within these components. A diversity of activities could be supported, such as pilot research projects, research projects, research training activities for their own students and programs for college students coming for summer research training from other institutions. New faculty could be hired, some even for research professorships which would involve little if any teaching responsibility. Major pieces of equipment could be purchased to allow the development of centers focussing a major effort in a chosen research area. Collaborative interdepartmental programs could also be devised and supported. Also support for conferences and workshops would be available, leading toward the enhancement of the biomedical research environment in a wide variety of areas.

Institutions choosing this third approach would develop a long-range program coordinating a major MSBS program with other plans and programs for the general strengthening of the institution in a number of major components. The level of award granted for this purpose could amount to perhaps $2,500,000 for an applicant institution over a five-year period.

B. Categories of Grantee Institutions

Institutions that apply under the MSBS program shall generally fall into one of three operating categories.

1. Category A

This category embodies baccalaureate degree-granting institutions only.

2. Category B

This group consists of institutions that award up to a Master's degree in one or more of the scientific disciplines.

3. Category C

This category embodies the minority institutions that offer science doctoral and/or medical, dental, and other health professional doctoral degrees.

C. Basis for Choosing Among Approaches

Any institution in the Categories described above could theoretically select any one of the three approaches in applying for a MSBS grant. Furthermore, under the Second Approach an institution might include a minor element in its proposal encompassing the philosophy of the First Approach. Likewise, an institution selecting the Third Approach might have some elements of the other two approaches within its general proposal.

From a practical standpoint, it should be relatively clear to an institution which approach is the most appropriate one to choose. In an institution which is primarily concerned with teaching per se, and in which only a few island of research now exist, it is not likely to be to the interest of the institution to distort the balance of its general missions and objectives as an institution by suddenly seeking to engage very heavily in biomedical research. Conversely, an institution with many faculty and students actively engaged in research would undoubtedly choose the Third Approach.

Therefore, again recognizing these considerations, it is expected that most institutions in Category A are likely to choose the First Approach, in Category B the Second Approach, and in Category C the Third Approach.

Institutions choosing not to follow the suggested approaches must provide the General Research Support Branch, Division of Research Resources, National Institutes of Health, with substantial justification and convincing evidence that an alternate approach will be in the best interest of the school in pursuit of its goals in the area of biomedical research and research training.

D. Size of Annual Budget Requests

Whatever the level of support sought, the institution is expected to develop a proposal which will specify the value of an MSBS program to its balance of missions and objectives. Also, the level of funds sought for each year of the program should (a) conform to a realistic assessment by the institution of its relative interest and capabilities in biomedical activities, and (b) reflect a plan for the orderly initiation, continuation, and conclusion of its MSBS program.

An institution should not normally plan a budget for its MSBS program which will be almost constant for each year, although this may be the case in the First Approach. During the initial year, the level of the budget will generally be rather modest. As the program continues into its second and third year (especially in the more broad-gauge programs) the budget for a program should grow rapidly due to the addition of new personnel, etc. As the program proceeds, investigators should begin seeking and hopefully receiving research support from other sources. The institution, anticipating this, should therefore expect that its fund requirements are likely to reduce gradually in the fourth and fifth years.

Each institution's budget pattern will develop in accord with many factors, so that no two patterns are likely to be exactly comparable. However, based on the trend which may be expected to develop, an institution's budget formulation may follow in a general way one of the following patterns, depending on the approach selected:

Year of Program	First Approach	Second Approach	Third Approach
First Year	$30,000	$ 80,000	$300,000
Second Year	45,000	120,000	500,000
Third Year	40,000	140,000	700,000
Fourth Year	40,000	120,000	600,000
Fifth Year	35,000	90,000	400,000

The above figures are presented for illustrative purposes only. The General Research Support Branch, Division of Research Resources, does not expect or require institutions necessarily to follow these patterns in developing budget requests; the levels shown are not to be construed as suggesting either the minimum or the maximum amounts to be used in MSBS applications. Each applicant is expected to present a budget request that is necessary and sufficient to carry out its MSBS program.

IV. PROCEDURES FOR APPLICATION, REVIEW, AND EVALUATION

Participation in the MSBS program does not preclude an institution from seeking financial support for other programs which can be sponsored by the National Institutes of Health or other Federal and non-Federal agencies. Also, enhancement of an institution's research environment because of its MSBS program should actually result in an increase in applications for other grant support.

An application kit, or further information, may be obtained from:

Minority Schools Biomedical Support Program
General Research Support Branch
Division of Research Resources
National Institutes of Health
Bethesda, Maryland 20014

Telephone: 301 - 496-6743

With the exception of a university with campuses in different communities, only one MSBS application can be submitted by an academic institution for review at one time, although an applicant institution may seek coordinated support for separate activities within different departments, schools, and/or colleges within the institution.

In addition to submitting a separate application, an institution may wish to participate in a proposal for a consortium of activities involving two or more separate institutions.

The application must have the approval of the chief executive officer of the institution (College or University President or Chancellor).

Applications judged to be incomplete, or considered not to comply with MSBS policies will be returned to the applicant for additional information or for revision. For this reason, discussions with the staff of the General Research Support Branch are encouraged prior to the formal submission of a MSBS application as an aid to the applicant in the effective presentation of program substance and for compliance with administrative requirements.

All awards are competitive; however, competition will be among ethnic minority institutions only. Each acceptable application will be thoroughly reviewed by the General Research Support Branch staff and consultants (including minority representation) to ascertain the soundness of the proposal, and to assess the benefits which can be expected to accrue both to the institution and to the national effort in biomedical research and research training. When necessary, the review process will involve a site visit by consultants and staff prior to the review and recommendation by the General Research Support Program Advisory Committee, and the National Advisory Research Resources Council.

Applications that are approved but unfunded may be allowed to remain in competition for an award, with or without additional review, for a period of one year or they may be revised and resubmitted by the applicant. Such applications, whether or not revised, must compete on an equal basis with all other current applications. No special status is given to previously approved but unfunded applications.

Additional funds needed to expand a program can be requested as a supplement during any portion of the project period. If awarded, the supplement becomes a part of the original grant to which it is a supplement. Although a program may be expanded through this mechanism, the request is subject to the same conditions and processed in the same manner as new applications and must compete for available funds.

Two months before the expiration of a current budget period, the grantee is required to submit to the General Research Support Branch an Interim Narrative Progress Report, simultaneously with the annual request for continuation support of the grant. The purpose of the Annual Report is to describe the activities carried out under the grant and the progress that has been made in achieving the intended goals of the institutional program.

An Interim Narrative Progress Report will not be requested for the final year of the grant, but a Final Narrative Progress Report covering the entire project period will be required within 90 days after the close of the project period.

An Annual Expenditures Report must be submitted within 90 days after the end of each budget period. The purpose of the Annual Expenditures Report is to provide specific fiscal information on expenditures and obligations incurred during the budget period. Forms and instructions for the completion of these reports will be provided to grantee institutions by the General Research Support Branch.

In the evaluation of MSBS applications, especially those from state-supported and other public institutions, priority will be given to support of program elements which will establish a resource of unique benefit to the general community served by those institutions and other like public institutions; moreover, at public institutions, program elements which are not of a nature essential to a basic educational program and which are substantially similar to those available in other public institutions serving the same general community shall not be funded.

V. GENERAL CONDITIONS OF AWARD

A. Nature and Amount of Awards

The applicant must specify the total period of time, up to five years, for which funds are sought (the project period), and must indicate the amount of funds in each budget category which is sought for each twelve-month segment (budget period) of the project period. In accordance with general NIH policy, the maximum length of a project period for a single program as requested may not exceed five years.

After review and approval, the initial Notice of Grant Awarded will specify (a) the total approved length of time for the project (the project period), (b) the total recommended amount of funds which may be awarded for the entire project period, and (c) the budget as approved for the first budget period (normally 12 months). The Notice of Grant Awarded will also specify the amount of funds awarded by the General Research Support Branch; the first award will normally coincide with the budget for the first budget period.

When the grantee institution has other Department of Health, Education, and Welfare (DHEW) awards paid through the National Institutes of Health payment system, payment of this grant will be incorporated into the same system.

If necessary, the institution should contact the following office for additional information:

Federal Assistance Financing Branch
Office of Financial Management
National Institutes of Health
Westwood Building
Bethesda, Maryland 20014

Telephone: 301 - 496-7041 or 301 - 496-7871

B. Non-competing Continuation Awards

Future awards for continuation years will be made annually, subject to availability of funds appropriated by the Congress, and subject to review and determination of satisfactory progress and continuing need. Application forms for continuation awards will be furnished to the grantee institution prior to the start of each budget period, and are expected to be submitted for review and negotiation no later than two months before the expiration of the current budget period. Such non-competing continuation award applications will not compete with applications for initial support received from other institutions.

The non-competing continuation application must specify in detail the budget, by budget category, required to carry out the program for the next budget period. In addition, the application should include an estimate of unexpended funds as of the end of the current budget period. Such unexpended funds will normally be carried forward and their expenditures authorized for the succeeding budget period, but may be used only within the limits of the budgets for the budget periods covered by these awards. The funds carried forward will be taken into consideration in determining the amount of additional funds required for the continuation award. Unexpended funds in excess of the estimate cannot be expended without further negotiation and prior approval of the General Research Support Branch.

C. Fiscal Data

Upon notification of an award, separate accounts must be established and maintained by the grantee to record appropriate receipts and disbursements of MSBS funds. All fiscal documents and accounts concerning the financial management of the grant, including the reported obligations and expenditures, are subject to audit verification for conformity with both the fiscal policies of the grantee institution and those of the Department of Health, Education, and Welfare.

D. Administration of the Award

1. The Program Director

The MSBS Program Director designated by the institution must be scientifically trained and must have had research experience. He will be responsible for the overall execution of the MSBS program; among his responsibilities are the following:

- ... To relate to the staff members participating in the MSBS program;
- ... To formulate guidelines for making funds available to MSBS participants in accordance with the proposed budget;
- ... To outline the level of responsibility that staff members must have for the details of the projects they undertake;
- ... To establish and maintain the mechanism to be followed for spending funds in accordance with the program objectives; and
- ... To assure that the staff members are able to carry out the activities in line with the proposal.

The Program Director will, in many instances, be substantially involved in the operational aspects of the program. He should have a broad perspective of, and insight into, institutional affairs, so that the MSBS program activities are coordinated and consistent with the overall objectives and missions of the institution.

An important role of the Program Director is to provide leadership in directing program activities commensurate with those outlined in the MSBS proposal. While the program provides for considerable flexibility in the use of the grant in general, it is expected to follow the course proposed.

The institution may select a suitably constituted committee to advise the Program Director and the head of the institution on matters pertaining to the MSBS program.

2. Governing Policy Statements

In general, the program will be administered in accordance with the Public Health Service policies as stated in "Grants for Research Projects" (PHS Publication No. 1301), "Grants for Training Projects" (PHS Publication No. 1302), and "NIH Guides for Grants and Contracts." In some instances, policies contained in this Minority Schools Biomedical Support Policy and Information Statement may differ from those in the documents mentioned above; in such cases, the policies contained in this Statement will govern.

E. Allowable Costs

1. General Statement

Grant funds may be used for payment of any relevant direct biomedical research and research training expense under the MSBS program except for those costs listed under Section V F, page 22, "Types of Charges Not Allowed," or classified as unallowable in the "Policy Statements" for "Grants for Research Projects," and "Grants for Training Projects," and the "Guides for Grants and Contracts." Prior approval of authorized expenditures is not necessary except for the limitations expressed in Section V G, page 22, "Prior Approval of Expenditures."

2. Administrative Costs

Since the provisions of the Labor-DHEW Appropriations Act specifically forbid the use of MSBS funds for indirect costs, the usual institutional administrative costs (which are treated by the institution as indirect costs and included in its indirect cost rate determination) are not allowable costs. However, some costs which are specifically identified to and chargeable to the MSBS program are allowable even though like costs for other institutional activities are treated as indirect costs. Thus, salary charges are allowable for the Program Director for that portion of his time or effort which is specifically employed in the direction of the MSBS program, or in some other capacity which likewise involves his personal participation in the research and research training of the MSBS program. Salaries of research secretaries and other similar personnel are allowable on the same basis.

Care must be taken to assure that administrative costs are not excessive, but that they are reasonably proportional to the size and complexity of the program. Also, they cannot be duplicated in any other allocation of the institution's costs, such as its pool of indirect costs. Because of the fact that such costs are usually administrative, the grantee institution must take special care to document clearly the direct relation to the program of the services involved.

General costs such as for utilities, janitorial services and other general maintenance, and like administrative costs, cannot be charged to the program on a pro rata basis such as laboratory square footage, number of persons involved or salaries paid, amount of equipment purchased, or number of items of equipment purchased, or through the application of other formula methods of proportioning these costs between activities. The General Research Support Branch should be consulted in case of doubt about the distribution of such costs.

3. Normal Research Costs

Although the Research Projects and Training Projects Policy Statements cited above list many allowable cost categories, a number of the normal allowable research costs which will be encountered are as follows:

a. Faculty salary support, in proportion to the time or effort spent on the MSBS program, including "released time."

b. Summer or off-quarter salary support, including full salary at the regular institutional rate when a faculty member is engaged full-time in research and/or research training.

c. Salary for research assistants and laboratory assistants, including undergraduate and graduate students selected for participation in the program (see also Section V.E. 5. regarding stipends for undergraduate, graduate, and postgraduate trainees).

d. Equipment necessary to the conduct of the program, and the cost of service contracts, repairs, and modifications to any research equipment used on the program.

e. Supplies, including chemicals, biological materials, animals, glassware, and other like items.

f. Travel which will provide direct scientific benefit to the program, including student and faculty attendance at scientific meetings.

g. Publication costs, including page costs and other expenses associated with the preparation and publication of articles describing the results of research activities supported by the program.

h. Books and periodicals, where they are directly related to appropriate biomedical research and research training projects.

i. Research training costs, including expenses directly related to undergraduate and graduate special research project courses.

j. Consultant services, including visiting scholars who will interact with students through research seminars and other relevant activities.

4. Alterations and Renovations

Request for support of alterations and renovations (A&R) may be included in a MSBS proposal only if essential to the conduct of the approved program. Such expenditures, if approved, must be made in accordance with NIH policy regarding the use of research and research training grant funds for A&R. However, the aggregate cost for the MSBS project period may not exceed the lesser of $75,000 or 25% of the total funds approved for the entire project period regardless of the number of separate A&R projects to be supported. There is no requirement for matching funds. (The General Research Support Branch should be contacted prior to the submission of the MSBS application if alterations and renovations projects are to be included as a part of the MSBS proposal.)

Alteration and renovation costs charged to grants to which this policy applies shall be limited to the costs of modifying existing space and utilities within a completed and finished structure. The cost of adapting any of the following building features to the needs of the grant supported activity are allowable:

... Work which adapts the physical characteristics of the space (interior dimensions, surfaces, finishes and furnishings, e.g., venetian blinds, and tile flooring--not furniture) to the needs of the institution's research and research training program. Equipment including fixed equipment, e.g., laboratory benches, may be purchased with MSBS funds, but are not considered a part of the alterations and renovations cost.

... Work which adapts the utility services (such as plumbing, electrical power, laboratory services--air, vacuum, gas) to the needs of the institution's research and research training program.

... Work which adapts the environment of the space (such as temperature control, air conditioning, ventilation, heating, acoustical treatment, etc.) to the needs of the institution's research and research training program.

Pursuant to the grantee's accounting system, certain costs of installing equipment may be listed as either equipment costs or alteration and renovation costs. These include the temporary removal and replacement of wall sections, door frames, etc., in order to place equipment in its permanent location. The costs of connecting utility lines, replacing finishes and furnishings, and installing any accessory devices required for the equipment's proper and safe utilization may be considered either equipment costs or alteration and renovation costs. Structural changes (e.g., permanent relocation of a partition as opposed to its temporary removal and replacement) must be shown as alteration and renovation costs.

5. Stipends and Other Research Trainee Support

Undergraduate, graduate, and postgraduate trainee stipends and support for related equipment and supplies can be provided in accordance with policies in the NIH "Policy Statement" for "Grants for Training Projects" for specifically justified biomedical research training. The number and type of trainees must be specified in the application, and the stipends, if any, for undergraduate trainees are subject to negotiation.

A distinction must be made between research trainees and research and laboratory assistants (see Section V.E. 3.c.). Trainees are considered to be engaged primarily in a formalized training experience and the purpose of their activity is to learn; research and laboratory assistants, on the other hand, are primarily engaged in assisting in the performance of research and any learning experience, while desirable, is incidental to the work performed. A further distinction must be made between research trainees (who may be supported on the MSBS program) and research fellows (who are only supported through the Postdoctoral and Special Fellowship programs of the NIH Institutes and Divisions).

Short-term support of relevant biomedical research training activities is also acceptable in instances where the existing faculty plus newly recruited faculty resulting from a MSBS award enables a department, previously lacking in number and variety of faculty for an adequate training and teaching program, to offer a high-quality and suitably balanced research training experience.

Also appropriate is the support of broadly-based training programs encompassing a focused research training activity of a multidisciplinary nature (which may involve several departments or schools) in a newly emerging field for which there is no available and appropriate NIH research training support mechanism.

Regular, full-time students in programs leading to professional degrees in health professional schools (e.g., M.D., D.D.S., D.O., or D.V.M.) may be supported in full- or part-time biomedical research training that is pertinent to the MSBS program, provided that such training is not a part of the research, course, or laboratory work required for the professional degree. Costs incurred for activities devoted to fulfilling requirements for the professional degree cannot be reimbursed from this award.

For full-time students enrolled in programs leading to graduate research degrees and baccalaureate degrees, MSBS funds may be used to reimburse costs of biomedical research training whether or not such costs are incurred in fulfilling the requirements for the degree.

Funds for the MSBS program may be used to support full-time undergraduate students as trainees if they are enrolled in a research training program; they may receive full-time stipends only while their participation in the training program is on a full-time basis. Among the types of activity that may involve research training are summer research training programs and/or special research project courses during the academic year.

A Statement of Appointment, Form PHS-2271, is required at the time of appointment for each trainee. Each Form should report only those expenditures that are anticipated for payment in relation to any given budget period of the MSBS award, and must be amended, if necessary, to correspond with the actual payments that are finally reported on the Annual Expenditures Report. A Statement of Appointment Form can apply only to one MSBS award budget period; therefore, if a trainee's appointment overlaps more than one budget period, a separate form for the trainee must be submitted for each budget period. Continuing expenditures for trainee stipends beyond the close of a budget period are to be reported in the following year's Expenditures Report.

MSBS funds cannot be used to supplement stipends provided by other Federal grants.

F. Types of Charges Not Allowed

1. Indirect Costs

These costs are the usual institutional administrative costs which cannot readily be ascribed to individual and specific activities within an institution and are therefore allocated between activities using some formula, such as salaries and wages associated with the activities. The following typical administrative costs are not allowable: salary of a Dean, an Assistant Dean of Research or a similar administrative official, salary of administrative secretaries, bookkeeping, personnel record keeping, purchasing, and general housekeeping services. As stated in Section V.E. 2, administrative personnel salaries can only be allowed for the time or effort involving their personal participation in the research and research training of the MSBS program.

2. Disapproved Proposals

MSBS funds may not be used for the support of projects specifically disapproved after undergoing the dual review process of an NIH Institute or Division. Activities that have not been funded by NIH although approved through the review process may be supported to the extent that they are an important element of the MSBS program.

3. New Construction

This includes completion of unfinished space, erection or relocation of outside walls, roofs, or floors; excavation, lead-in lines for utilities or services to existing buildings, etc.

4. Routine Maintenance and Repairs

This includes the institution's physical plant or its non-research equipment.

5. Installation

This includes the installation of utilities in an unfinished shell space, furnishings, or finishes so as to make the area suitable for human occupancy. These limitations do not preclude modifying such space to make it suitable for purposes other than for human occupancy; for example, the storage of chemicals, supplies, and pharmaceuticals, etc.

6. Multiple Purpose Travel

Such travel is not allowable even though research, or research training, is one of the purposes of the travel. (However, travel such as to scientific meetings and conferences is allowable as specified in the research and research training grant Policy Statements.)

7. Library Support

Binding costs are considered library support and are not allowable. (However, as stated in Section V.E. 2.h., the costs of books and periodicals directly related to biomedical research and research training projects are allowable.)

G. Prior Approval of Expenditures

Prior approval from the staff of NIH is not necessary for allowable expenditures, except for:

... Research and research training activities that have undergone the dual NIH review process and have been disapproved.

... Unexpended funds carried over into a new budget period in excess of the funds previously estimated to be unexpended.

... Printing equipment.

... Items specifically restricted by the "Notice of Grant Awarded" issued for each individual grant.

Except for the restrictions stated above, funds may be transferred between budget categories, without prior approval, for minor changes made during a budget period. The policy is to provide the grantee institution with as much program and administrative autonomy as is feasible, provided that the intent of the MSBS program is not negated.

H. Cost Sharing

Under provisions of the Labor-DHEW Appropriations Act, indirect costs are not allowable in the MSBS program; therefore, the formal requirements of the Department of Health, Education, and Welfare for cost sharing do not apply, because the statutory requirement for cost sharing is fulfilled through indirect costs.

I. Publications

All publications resulting from research supported by a MSBS award should acknowledge NIH support with the following or a comparable footnote:

> "This investigation was supported by Grant RR-____, from the General Research Support Branch, Division of Research Resources, National Institutes of Health."

DIVISION OF RESEARCH RESOURCES
GENERAL RESEARCH SUPPORT BRANCH
NATIONAL INSTITUTES OF HEALTH

Addendum to Minority Schools Biomedical Support (MSBS) Program General Policy and Information Statement

I. Program Title

The new title is: Minority Biomedical Support Program (MBS)

II. Goals of the Program

A. To increase the numbers of ethnic minority faculty, students, and investigators engaged in biomedical research.

B. To broaden the opportunities for participation in biomedical research of ethnic minority faculty, students, and investigators.

C. To assist in the provision of an appropriate setting in which the above two goals can best be accomplished.

Eligibility

To be eligible for a grant under this Program, an applicant must be:

A. One of the following:

1. A public or private nonprofit university, four year college, or other institution offering undergraduate, graduate, or health professional degrees with a student enrollment derived primarily from ethnic minorities;
2. A public or private nonprofit two year college, with a student enrollment derived primarily from ethnic minorities;
3. A public or private nonprofit university, four year college, or other institution offering undergraduate, graduate, or health professional degrees, with a student enrollment a significant proportion (but not necessarily a majority) of which is derived from ethnic minorities, provided the Secretary (DHEW) determines that said institution has a demonstrated commitment to the special encouragement of and assistance to ethnic minority faculty, students, and investigators; or
4. A Native American Indian Tribal Council; and

B. Located in a State, the District of Columbia, Puerto Rico, the Virgin Islands, the Canal Zone, Guam, American Samoa, or the U.S. Trust Territory of the Pacific Islands.

4/25/75

Appendix E

NATIONAL HEART AND LUNG INSTITUTE

YOUNG INVESTIGATOR RESEARCH GRANT

OBJECTIVES

The Young Investigator Research Grant Program is intended to:

- encourage independent investigators to develop their research interests in the cardiovascular, pulmonary, and blood disease areas;
- provide support for the initial research effort of investigators in these areas, so that they can explore their own research ideas;
- foster an overall expansion of new research ideas in both fundamental and clinical areas.

This program would expand the concept of the Young Investigator Pulmonary Research Grant to cover all areas for which the National Heart and Lung Institute is responsible.

RATIONALE

Despite a recent decline in the death rate from coronary heart disease, cardiovascular disease continues to be the number-one killer in the United States. Arteriosclerosis and hypertension account for over one million deaths annually. An estimated 30 million Americans have diseases of the heart and blood vessels, resulting in a large burden of acute and chronic illness and disability. Heart and blood vessel diseases cost the economy more than $40 billion per year in wages, lost productivity, and expenses for medical care.

Diseases of the lung constitute a major national health problem. An estimated 10 million Americans, both young and old, are currently affected by these diseases with an annual estimated cost to the nation of over $17 billion. In the newborn, the most common cause of death is neonatal respiratory distress syndrome. Neonatal RDS is implicated in the development of adult respiratory diseases, as well. Fibrotic and immunologic lung diseases are a major cause of lung problems in the young adult and may cause chronic obstructive pulmonary disease. Of the adult respiratory diseases, emphysema and chronic bronchitis are the major causes of death. Together with asthma, emphysema and chronic bronchitis represent a particularly pressing health problem, since the death rate and prevalence of these conditions have increased at an alarming rate over the past 15 years. As a disabling disease, emphysema is the third leading cause of worker retirement on social security disability payments.

Bleeding and clotting disorders underlie or are a major contributor to many disease processes and, as a consequence, are a major cause of death and disability in the United States. No valid estimate of its adverse economic impact can be realistically made, since disorders of the blood not only affect the blood itself, but all of the organs and tissues through which it flows. Similarly, when estimating the economic consequences of an inadequate blood resource system, quantitative figures are impossible to determine, since the supply and management of blood and blood products underlie much routine and emergency medical practice. A small but significant segment of the population has Sickle Cell Anemia or other hemolytic diseases; however, the economic impact of these, too, is serious.

The Young Investigator Research Grant Program is designed to encourage young investigators who are in basic or clinical science disciplines to channel their interests and capabilities into research related to the programs of the National Heart and Lung Institute. To help bridge the transition from an in-training status to that of a productive investigator, this special grant program would provide support for young scientists and physicians with meritorious research ideas of their own design. This opportunity for initial research support should attract talented young scientists to the challenging research problems presented by cardiovascular, lung, and blood diseases and particularly those emphasized in the national plan of the National Heart and Lung Institute.

When the Young Investigator Research Grant Program is announced, a special effort will be made to reach the physician or biomedical scientist who wishes to establish independent research support for the first time.

IMPLEMENTATION

Beginning in fiscal year 1977, the Institute proposes to award not more than 150 new Young Investigator Research Grants each year, each with a duration of not more than 2 years. When recommended for 2 years, funding for the second year of the grant will be contingent on satisfactory progress during the preceding year. The total funds for Young Investigator Research Grants newly awarded in fiscal year 1977 will not exceed $4,500,000 for direct costs.

The status of the Young Investigator Research Grant Program will be reviewed 3 years from the date of the first awards to determine whether or not the program should be continued.

To assess the effectiveness of the program in fulfilling its objectives, the Institute intends, after termination of each grant, to follow the progress of the recipient for a period of 6 years to determine (1) the investigator's professional affiliation(s), (2) his/her subsequent grant or contract support, and (3) his/her scientific publications.

It is anticipated that the results achieved with this grant will, in a majority of cases, provide the basis for successful competition in the regular grant program.

The receipt date for applications will be November 1 and they will be reviewed at the May meeting of the National Heart and Lung Advisory Council. July 1 will be the starting date. Applications will be submitted on form NIH 398.

CRITERIA FOR ELIGIBILITY

The project must be

- relevant to problems of cardiovascular, pulmonary, or blood diseases;
- a well-defined study to answer a specific scientific question, or a pilot study, but not supplemental to a project supported by other funds;
- designed for completion within a 2-year period;
- acceptable in accordance with the customary criteria of scientific merit.

The investigator must

- provide a satisfactory plan for completing the project within 2 years;
- submit with the application the names of three persons who are present or past supervisors or preceptors and who will forward letters attesting to his/her ability to undertake the project;
- have a doctoral degree by the time of the award;
- be a citizen or a non-citizen national of the United States or its possessions and territories, or have been lawfully admitted to the United States for permanent residence at the time of submitting the grant application;
- agree to keep the National Heart and Lung Institute informed about scientific accomplishments, change in professional status and change in institutional affiliation for a period of 6 years after the grant terminates;
- not be the recipient of an NIH Special Fellowship, Research Career Development Award, nor have been the principal investigator on a research grant, research contract, or the equivalent, either at present or in the past; however, trainees or regular research fellows are not excluded;

- not receive salary support from a National Institutes of Health center grant, program project grant, regular research grant, or research contract during the first year of the Young Investigator Research Grant;
- agree to devote at least 30 percent of his/her time to the project.

The applicant institution, through the chairperson of the sponsoring department, must

- indicate its commitment to the project;
- provide space and facilities necessary to pursue the project;
- release the principal investigator from other responsibilities for the proportion of time or effort to be devoted to the project.

Institutions may submit more than one application, but only domestic institutions may apply.

SUPPORT PROVIDED BY THE GRANT

The Young Investigator Research Grant will provide support for a period of up to 2 years in an amount not to exceed $50,000 direct costs, of which no more than $30,000 may be requested for the first 12-month period. These grants are not renewable and because of their special nature, certain limitations are placed on the items which can be supported, as specified below.

Personnel

- salary and fringe benefits for the principal investigator may be requested to the extent that they reflect the time or effort expected to be devoted to the project. The effort of one part-time technical assistant may also be supported, if justified in terms of the research.

Consultant services

- support may not be requested.

Equipment

- the facilities should include most of the necessary equipment. Some specialized equipment essential to the specific research effort may, however, be justified. The cost may not exceed $5,000 and may only be requested for the start of the effort.

Supplies

- the cost of necessary supplies must be detailed and justified.

Travel

- expenses to attend one national meeting closely related to the project may be requested for each 12-month period.

Hospitalization

- support for patient expenses of any kind must be strongly justified if needed for the project.

Publication costs

- since publishable results are seldom expected in the first 12 months, usually publication costs will only be approved for the second portion of the project.

Other expenses

- if other items are necessary for performance of the research effort, these must be clearly justified in terms of that need.

Indirect costs

- will be provided in accordance with established DHEW agreements for regular research grants.

APPLICATION

Applications must be submitted on form NIH 398. The original copy and the folder in which it is submitted should be clearly labeled (in red ink) NHLI Young Investigator Research Grant. The proposed project should be presented using the format described in the "Instructions" in the application kit.

The chairperson of the department sponsoring the research should submit a signed statement as part of the application detailing the commitments made to the project.

The investigator should ask three present or former supervisors or preceptors to send a letter to the Division of Research Grants, NIH, attesting to his/her potential for conducting research, but these should not comment on the merit of this specific project.

Applications may be submitted prior to November 1 for final review at the following May meeting of the National Heart and Lung Advisory Council. Successful applicants may plan to initiate their research effort between July 1 and September 1.

Applications will be screened for relevance to the programs of the Institute in heart and vascular, lung, or blood diseases and resources. Scientific merit review will be arranged by the Review Branch, Division of Extramural Affairs, NHLI. Applicants will be informed of the results of this review by the first week in June.

Questions or requests for further information should be directed to the staff of the program area to which the research will be related. For reference, call area code 301, 496-7225.